

INVERNESS MEDICAL INNOVATIONS INC  
Form 10-Q  
November 08, 2006

**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, 2006

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**

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of  
accelerated filer and large accelerated filer in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

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

**Yes**  **No**

The number of shares outstanding of the registrant's common stock, par value of \$0.001 per share, as of November 3, 2006 was 38,793,930.

---

**INVERNESS MEDICAL INNOVATIONS, INC.**

**FORM 10-Q**

**For the Quarterly Period Ended September 30, 2006**

*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, 2005 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>PART I. FINANCIAL INFORMATION</b>	
<u>Item 1.</u>	
a)	<u>Consolidated Financial Statements (unaudited):</u> <span style="float: right;">3</span>
<u>Consolidated Statements of Operations for the Three and Nine Months Ended September 30, 2006 and 2005</u> <span style="float: right;">3</span>	
b)	<u>Consolidated Balance Sheets as of September 30, 2006 and December 31, 2005</u> <span style="float: right;">4</span>
c)	<u>Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2006 and 2005</u> <span style="float: right;">5</span>
d)	<u>Notes to Consolidated Financial Statements</u> <span style="float: right;">6</span>
<u>Item 2.</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> <span style="float: right;">35</span>
<u>Item 3.</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u> <span style="float: right;">53</span>
<u>Item 4.</u>	<u>Controls and Procedures</u> <span style="float: right;">55</span>
<b>PART II. OTHER INFORMATION</b>	
<u>Item 1A.</u>	<u>Risk Factors</u> <span style="float: right;">56</span>
<u>Item 2.</u>	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u> <span style="float: right;">56</span>
<u>Item 6.</u>	<u>Exhibits</u> <span style="float: right;">56</span>
<b>SIGNATURE</b>	<span style="float: right;">58</span>

**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, 2006</b>		<b>Nine Months Ended September 30, 2006</b>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Net product sales	\$ 140,896	\$ 101,808	\$ 400,246	\$ 289,280
License and royalty revenue	4,016	4,486	12,200	11,205
<b>Net revenue</b>	<b>144,912</b>	<b>106,294</b>	<b>412,446</b>	<b>300,485</b>
Cost of sales	83,767	66,659	250,551	193,948
<b>Gross profit</b>	<b>61,145</b>	<b>39,635</b>	<b>161,895</b>	<b>106,537</b>
Operating expenses:				
Research and development (Note 12)	16,025	7,996	39,749	20,587
Sales and marketing	25,986	17,660	69,498	52,356
General and administrative	18,090	14,401	51,606	44,758
Loss on dispositions, net (Note 11)			3,191	
<b>Operating income (loss)</b>	<b>1,044</b>	<b>(422 )</b>	<b>(2,149 )</b>	<b>(11,164 )</b>
Interest expense, including amortization of original issue discounts and write-off of deferred financing costs (Note 13)	(8,193 )	(5,457 )	(20,796 )	(15,430 )
Other (expense) income, net	(913 )	295	3,960	20,079
<b>Loss before provision for income taxes</b>	<b>(8,062 )</b>	<b>(5,584 )</b>	<b>(18,985 )</b>	<b>(6,515 )</b>
Provision for income taxes	1,621	988	3,884	5,355
<b>Net loss</b>	<b>\$ (9,683 )</b>	<b>\$ (6,572 )</b>	<b>\$ (22,869 )</b>	<b>\$ (11,870 )</b>
<b>Net loss per common share basic and diluted</b>				
<b>(Note 5)</b>	<b>\$ (0.27 )</b>	<b>\$ (0.25 )</b>	<b>\$ (0.70 )</b>	<b>\$ (0.51 )</b>
<b>Weighted average common shares basic and diluted (Note 5)</b>	<b>35,396</b>	<b>25,951</b>	<b>32,498</b>	<b>23,358</b>

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

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
**(unaudited)**  
**(in thousands, except per share amounts)**

ASSETS	September 30, 2006	December 31, 2005
<b>Current assets:</b>		
Cash and cash equivalents	\$ 74,572	\$ 34,270
Accounts receivable, net of allowances of \$8,634 at September 30, 2006 and \$9,748 at December 31, 2005	109,196	70,476
Inventories, net	87,006	71,209
Deferred tax assets	845	844
Prepaid expenses and other current assets	16,662	17,534
<b>Total current assets</b>	<b>288,281</b>	<b>194,333</b>
Property, plant and equipment, net	80,556	72,211
Goodwill	440,024	322,210
Other intangible assets with indefinite lives	67,480	63,742
Core technology and patents, net	74,285	64,050
Other intangible assets, net	93,175	60,489
Deferred financing costs, net and other non-current assets	12,253	13,013
Other investments	11,209	456
Deferred tax assets	803	662
<b>Total assets</b>	<b>\$ 1,068,066</b>	<b>\$ 791,166</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
<b>Current liabilities:</b>		
Current portion of long-term debt	\$ 1,768	\$ 2,367
Current portion of capital lease obligations	571	542
Accounts payable	63,087	42,155
Accrued expenses and other current liabilities	75,233	64,746
<b>Total current liabilities</b>	<b>140,659</b>	<b>109,810</b>
<b>Long-term liabilities:</b>		
Long-term debt, net of current portion	200,198	258,617
Capital lease obligations, net of current portion	548	978
Deferred tax liabilities	26,102	18,881
Other long-term liabilities	5,822	5,572
<b>Total long-term liabilities</b>	<b>232,670</b>	<b>284,048</b>
<b>Commitments and contingencies (Note 16)</b>		
<b>Series A redeemable convertible preferred stock, \$0.001 par value:</b>		
Authorized: 2,667 shares		
Issued: 2,527 shares at September 30, 2006 and December 31, 2005		
Outstanding: none at September 30, 2006 and December 31, 2005		
<b>Stockholders equity:</b>		
Preferred stock, \$0.001 par value		
Authorized: 2,333 shares		
Issued: none at September 30, 2006 and December 31, 2005		
Common stock, \$0.001 par value		
Authorized: 50,000 shares		
Issued and outstanding: 38,761 at September 30, 2006 and 27,497 shares at December 31, 2005	39	27
Additional paid-in capital	819,252	515,147
Notes receivable from stockholders	(4,026 )	(14,691 )
Accumulated deficit	(133,096 )	(110,227 )
Accumulated other comprehensive income	12,568	7,052
<b>Total stockholders equity</b>	<b>694,737</b>	<b>397,308</b>
<b>Total liabilities and stockholders equity</b>	<b>\$ 1,068,066</b>	<b>\$ 791,166</b>

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

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(unaudited)**  
**(in thousands)**

	<b>Nine Months Ended September 30, 2006</b>	<b>2005</b>
<b>Cash Flows from Operating Activities:</b>		
Net loss	\$ (22,869 )	\$ (11,870 )
Adjustments to reconcile net loss to net cash provided by operating activities:		
Interest expense related to amortization and write-off of non-cash original issue discount and deferred financing costs	3,252	1,660
Non-cash (income) loss related to currency	(217 )	212
Non-cash stock-based compensation expense	3,872	140
Charge for in-process research and development	4,960	
Depreciation and amortization	29,213	18,995
Deferred income taxes	1,860	1,915
Impairment of long-lived assets	9,143	
Other non-cash items	(1,517 )	(11 )
Changes in assets and liabilities, net of acquisitions:		
Accounts receivable, net	(25,019 )	8,480
Inventories	(8,607 )	(4,457 )
Prepaid expenses and other current assets	3,067	(3,942 )
Accounts payable	16,202	3,655
Accrued expenses and other current liabilities	(6,681 )	7,969
Other non-current liabilities	224	(124 )
<b>Net cash provided by operating activities</b>	<b>6,883</b>	<b>22,622</b>
<b>Cash Flows from Investing Activities:</b>		
Purchases of property, plant and equipment	(13,557 )	(14,662 )
Proceeds from sale of property, plant and equipment	2,217	172
Cash paid for acquisitions and transactional costs, net of cash acquired	(124,395 )	(139,681 )
Increase in other assets	(2,031 )	(1,375 )
<b>Net cash used in investing activities</b>	<b>(137,766 )</b>	<b>(155,546 )</b>
<b>Cash Flows from Financing Activities:</b>		
Cash paid for financing costs	(2,012 )	(2,648 )
Proceeds from issuance of common stock, net of issuance costs	231,333	95,956
Net (payments) proceeds under revolving lines of credit	(45,127 )	54,616
Net (repayments) borrowings of notes payable	(22,614 )	69
Payment received on notes receivable	10,665	
Principal payments of capital lease obligations	(409 )	(358 )
<b>Net cash provided by financing activities</b>	<b>171,836</b>	<b>147,635</b>
Foreign exchange effect on cash and cash equivalents	(651 )	(1,494 )
<b>Net increase in cash and cash equivalents</b>	<b>40,302</b>	<b>13,217</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>34,270</b>	<b>16,756</b>
<b>Cash and cash equivalents, end of period</b>	<b>\$ 74,572</b>	<b>\$ 29,973</b>
<b>Supplemental Disclosure of Non-cash Activities:</b>		
Fair value of stock issued for acquisitions and intellectual property	\$ 68,915	\$ 57,962

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

**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, 2005 included information and footnotes necessary for such presentation and were included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 15, 2006. 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, 2005.

**(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, 2006, 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, 2006</b>	<b>December 31, 2005</b>
Raw materials	\$ 31,205	\$ 25,488
Work-in-process	24,920	17,812
Finished goods	30,881	27,909
	<b>\$ 87,006</b>	<b>\$ 71,209</b>

**(4) Stock-Based Compensation**

Effective January 1, 2006, we began recording compensation expense associated with stock options and other forms of equity compensation in accordance with Statement of Financial Accounting Standards ( SFAS ) No. 123-R, *Share-Based Payment*, as interpreted by SEC Staff Accounting Bulletin ( SAB ) No. 107. Prior to January 1, 2006, we accounted for stock options according to the provisions of Accounting Principles Board ( APB ) Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations, and therefore no related compensation expense was recorded for awards granted with no intrinsic value. We adopted the modified prospective transition method provided for under SFAS No. 123-R, and consequently have not retroactively adjusted results from prior periods. Under this transition method, compensation cost associated with stock options now includes: (i) amortization related to the remaining unvested portion of all stock option awards granted prior to January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123, and

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

(ii) amortization related to all stock option awards granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123-R. In addition, we record expense over the offering period in connection with shares issued under our employee stock purchase plan. The compensation expense for stock-based compensation awards includes an estimate for forfeitures and is recognized over the expected term of the options using the straight-line method.

In accordance with SFAS No. 123-R, as of September 30, 2006, our results of operations for the three and nine months ended September 30, 2006 reflected compensation expense for new stock options granted and vested under our stock incentive plan and employee stock purchase plan and the unvested portion of previous stock option grants which vested during the three and nine months ended September 30, 2006. Stock-based compensation expense in the amount of \$1.3 million and \$3.9 million was reflected in our consolidated statements of operations for the three and nine months ended September 30, 2006, respectively, as follows (in thousands):

	<b>Three Months Ended September 30, 2006</b>	<b>Nine Months Ended September 30, 2006</b>
Cost of sales	\$ 89	\$ 284
Research and development	301	858
Sales and marketing	101	444
General and administrative	823	2,272
	<b>\$ 1,314</b>	<b>\$ 3,858</b>

Prior to our adoption of SFAS No. 123-R, we reported all tax benefits resulting from the exercise of stock options as operating cash flows in our consolidated statements of cash flows. In accordance with SFAS No. 123-R, for the three and six months ended September 30, 2006, the presentation of our cash flows has changed from prior periods to report the excess tax benefits from the exercise of stock options as financing cash flows. For the three and nine months ended September 30, 2006, no excess tax benefits were generated from option exercises.

For stock options granted prior to the adoption of SFAS No. 123-R, if expense for stock-based compensation had been determined under the fair value method of the original SFAS 123 for the three and nine months ended September 30, 2005, our net loss per common share would have been adjusted to the following pro forma amounts (in thousands, except for per share data):

	<b>Three Months Ended September 30, 2005</b>	<b>Nine Months Ended September 30, 2005</b>
Net loss as reported	\$ (6,572 )	\$ (11,870 )
Stock-based compensation as reported		140
Pro forma stock-based compensation	(1,853 )	(4,825 )
Net loss pro forma	\$ (8,425 )	\$ (16,555 )
Net loss per common share:		
Basic and diluted as reported	\$ (0.25 )	\$ (0.51 )
Basic and diluted pro forma	\$ (0.32 )	\$ (0.71 )

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

Our stock option plans provide for grants of options to employees to purchase common stock at the fair market value of such shares on the grant date of the award. The options vest over a four year period, beginning on the date of grant, with a graded vesting schedule of 25% at the end of each of the four years. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing method. We use historical data to estimate the expected price volatility and the expected forfeiture rate. For the three and nine months ended September 30, 2006, we have chosen to employ the simplified method of calculating the expected option term, which averages an award's weighted average vesting period and its contractual term. The contractual term of our stock option awards is ten years. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant with a remaining term equal to the expected term of the option. We have not made any dividend payments nor do we have plans to pay dividends in the foreseeable future. The following assumptions were used to estimate the fair value of options granted during the three and nine months ended September 30, 2006 and 2005 using the Black-Scholes option-pricing model:

	<b>Three Months Ended</b>		<b>Nine Months Ended</b>					
	<b>September 30,</b>	<b>2006</b>	<b>September 30,</b>	<b>2006</b>	<b>2005</b>			
<b>Stock Options:</b>								
Risk-free interest rate	4.00	%	3.83-3.98	%	4.00%-4.38	%	3.58-4.09	%
Expected dividend yield								
Expected life	6.25 years		5 years		6.25 years		5 years	
Expected volatility	42	%	45	%	42	%	45	%
<b>Employee Stock Purchase Plan:</b>								
Risk-free interest rate	4.99	%	3.71	%	4.99	%	3.71	%
Expected dividend yield								
Expected life	184 days		182 days		184 days		182 days	
Expected volatility	33.19	%	38.15	%	33.19	%	36.92	%

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

A summary of the stock option activity for the nine months ended September 30, 2006 is as follows:

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (in thousands)
Options outstanding, January 1, 2006	3,901,726	\$ 18.82		
Granted	286,500	\$ 27.01		
Exercised	(321,338 )	\$ 16.10		
Forfeited or expired	(244,199 )	\$ 21.50		
Options outstanding, September 30, 2006	3,622,689	\$ 19.53	6.50 years	\$ 55,484
Options exercisable, September 30, 2006	2,490,941	\$ 17.10	5.57 years	\$ 44,285

The weighted average fair value under the Black-Scholes option pricing model of options granted to employees during the nine months ended September 30, 2006 and 2005 were \$12.93 and \$12.05 per share, respectively.

As of September 30, 2006, the total remaining unrecognized compensation cost related to nonvested awards was \$10.3 million. The weighted average period over which the cost is expected to be recognized is 2.45 years.

**(5) Net Income (Loss) Per Common Share**

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

	Three Months Ended September 30, 2006		Nine Months Ended September 30, 2006	
<b>Numerator:</b>				
Net loss basic and diluted	\$ (9,683 )	\$ (6,572 )	\$ (22,869 )	\$ (11,870 )
<b>Denominator:</b>				
Denominator for basic net loss per common share weighted average shares	35,396	25,951	32,498	23,358
Effect of dilutive securities:				
Stock options				
Warrants				
Restricted stock and escrow shares				
Dilutive potential common shares				
Denominator for dilutive loss per common share adjusted weighted average shares	35,396	25,951	32,498	23,358
Net loss per common share basic and diluted	\$ (0.27 )	\$ (0.25 )	\$ (0.70 )	\$ (0.51 )

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

We had potential dilutive securities outstanding on September 30, 2006 consisting of options and warrants to purchase an aggregate of 4.3 million shares of common stock at a weighted average exercise price of \$19.09 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, 2006, because the effect of including the number of such potential dilutive securities would be antidilutive.

We had the following potential dilutive securities outstanding on September 30, 2005: (a) options and warrants to purchase an aggregate of 4.7 million shares of common stock at a weighted average exercise price of \$18.04 per share and (b) 104,000 shares of common stock held in escrow. These potential dilutive securities were not included in the computation of diluted net loss per share for the three and nine months ended September 30, 2005, because the effect of including the number of such potential dilutive securities would be antidilutive.

**(6) Comprehensive Income (Loss)**

We account for comprehensive income as prescribed by SFAS No. 130, *Reporting Comprehensive Income*. In general, comprehensive income (loss) combines net income (loss) and other changes in equity during the year from non-owner sources. Our accumulated other comprehensive income, which is a component of shareholders' equity, includes primarily foreign currency translation adjustments and is our only source of equity from non-owners. For the three and nine months ended September 30, 2006, we generated a comprehensive loss of \$6.4 million and \$17.4 million, respectively, and for the three and nine months ended September 30, 2005, we generated a comprehensive loss of \$8.9 million and \$20.3 million, respectively.

**(7) Stockholders' Equity**

On February 8 and 9, 2006, we sold an aggregate 3,400,000 shares of our common stock at \$24.41 per share to funds affiliated with 14 accredited institutional investors in a private placement. Proceeds from the private placement were approximately \$79.3 million, net of issuance costs of \$3.7 million. Of this amount, we repaid principal and interest outstanding under our senior credit facility of \$74.1 million, with the remainder of the net proceeds retained for general corporate purposes.

In connection with the February 2006 private placements of common stock, we registered the resale of the private placement shares by filing a registration statement on Form S-3 on May 30, 2006.

On August 23, 2006, we sold an aggregate 5,000,000 shares of our common stock at \$30.25 per share to funds affiliated with 17 accredited institutional investors in a private placement. Proceeds from the private placement were approximately \$145.5 million, net of issuance costs of \$5.7 million. Of this amount, we used \$41.3 million for payments related to our ABON acquisition, \$5.3 million to purchase the remaining 32.55% of CLONDIAG, repaid principal outstanding under our senior credit facility of \$54.0 million and repaid principal and interest outstanding, along with a prepayment penalty, under our 10% subordinated promissory notes of \$20.8 million, with the remainder of the net proceeds retained for general corporate purposes.

In connection with the August 2006 private placement of common stock, we agreed to use commercially reasonable efforts to register the resale of the private placement shares on or prior to November 21, 2006. In the event that we are unable to take a registration statement effective prior to

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

November 21, 2006, we will pay an illiquidity discount equal to 0.5% of the August 2006 aggregate purchase price per month until the earlier of (i) the date that the registration statement is declared effective or (ii) the second anniversary of the closing date.

**(8) Business Combinations**

Acquisitions are an important part of our growth strategy. When we acquire businesses, we seek to complement existing products and services, enhance or expand our product lines and/or expand our customer base. We determine what we are willing to pay for each acquisition partially based on our expectation that we can cost effectively integrate the products and services of the acquired companies into our existing infrastructure. In addition, we utilize the existing infrastructure and employees of the acquired companies to cost effectively introduce our products to new geographic areas. All of these factors contributed to the acquisition prices of the acquired businesses discussed below that were in excess of the fair value of net assets acquired and the resultant goodwill.

*Acquisitions*

*(a) Acquisition of Innovacon and the ABON Facility*

On March 31, 2006, we acquired the assets of ACON Laboratories business of researching, developing, manufacturing, marketing and selling lateral flow immunoassay and directly-related products in the United States, Canada, Europe (excluding Russia, the former Soviet Republics that are not part of the European Union, Spain, Portugal and Turkey), Israel, Australia, Japan and New Zealand ( Innovacon ). The preliminary aggregate purchase price was approximately \$91.6 million which consisted of \$55.1 million in cash, 711,676 shares of our common stock with an aggregate fair value of \$19.7 million, \$6.8 million in estimated direct acquisition costs and an additional liability of \$10.0 million payable to the sellers on the deferred payment date, pursuant to the purchase agreement. The fair value of our common stock was determined based on the average market price of our common stock pursuant to Emerging Issues Task Force ( EITF ) Issue No. 99-12, *Determination of the Measurement Date for the Market Price of Acquirer Securities Issued in a Purchase Business Combination*.

On May 15, 2006, we acquired a newly-constructed manufacturing facility in Hangzhou, China ( ABON ), pursuant to the terms of our acquisition agreement with ACON Laboratories, Inc. and its affiliates. In connection with the acquisition of the new facility, we acquired ABON BioPharm (Hangzhou) Co., Ltd ( ABON ), the direct owner of the new factory and now our subsidiary. The preliminary aggregate purchase price was approximately \$20.8 million which consisted of \$8.8 million in cash and 417,446 shares of our common stock with an aggregate fair value of \$12.0 million. The fair value of our common stock was determined based on the average market price of our common stock pursuant to EITF Issue No. 99-12. In addition, pursuant to the acquisition agreement, we made an additional payment of \$4.1 million in cash as a result of the amount of cash acquired, net of indebtedness assumed, which increased the preliminary aggregate purchase price to \$24.9 million.

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

On August 28, 2006, pursuant to the above agreement, we paid cash of approximately \$17.5 million and issued 463,830 shares of our common stock with an aggregate fair value of \$13.3 million upon the ABON facility being fully functional for the sale of products in the United States of America ( USA ). The fair value of our common stock was determined based on the average market price of our common stock pursuant to EITF Issue No. 99-12. On September 1, 2006, we paid cash of approximately \$13.8 million and issued 278,298 shares of our common stock with an aggregate fair value of \$8.0 million upon the ABON facility being fully functional for the sale of products in Europe. The fair value of our common stock was determined based on the average market price of our common stock pursuant to EITF Issue No. 99-12. Additionally, on September 27, 2006, we paid cash of approximately \$10.0 million upon the ABON facility achieving certain Chinese regulatory approvals. The August and September 2006 transactions resulted in an increase of \$62.6 million in the preliminary aggregate purchase price.

The aggregate purchase price of \$179.1 million, which includes the closing events discussed above, was preliminarily allocated to the assets acquired and liabilities assumed at the date of acquisition as follows (in thousands):

Cash	\$ 8,403
Accounts receivable	11,328
Inventories	4,814
Property, plant and equipment, net	10,274
Goodwill	115,087
Trademarks	5,000
Customer relationships	30,000
Supply agreements	5,000
Other assets	1,369
Accounts payable and accrued expenses	(4,081 )
Long-term debt	(8,125 )
	\$ 179,069

The above values for the assets acquired and liabilities assumed are based on preliminary management estimates due to the timing of the acquisition. Final purchase price allocation may differ from the above. Management is also in the process of determining the useful lives of the intangible assets, as listed above.

The acquisition of Innovacon and ABON are accounted for as purchases under SFAS No. 141, *Business Combinations*. Accordingly, the operating results of Innovacon and ABON will be included in our consolidated financial statements from the acquisition date as part of our consumer and professional diagnostic products reporting units and business segments. Goodwill generated from this acquisition is not deductible for tax purposes.

*(b) Acquisition of CLONDIAG*

On February 28, 2006, we acquired 67.45% of CLONDIAG chip technologies GmbH ( CLONDIAG ), a privately-held company located in Jena in Germany which has developed a multiplexing technology for nucleic acid and immunoassay-based diagnostics. Pursuant to the acquisition agreement, we purchased the remaining 32.55% on August 31, 2006. The aggregate purchase price was \$23.0 million, which consisted of an initial cash payment of \$11.9 million, 218,502 shares of our common

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

stock with an aggregate fair value of \$5.8 million and a \$5.3 million cash payment to acquire the remaining 32.55% stock ownership. The fair value of our common stock issued was determined pursuant to EITF Issue No. 99-12. Additionally, pursuant to the terms of the acquisition agreement, we assumed an obligation to settle existing employee bonus arrangements with the CLONDIAG employees totaling 1.1 million (\$1.3 million). In connection with this obligation, we issued 24,896 shares of our common stock with a fair value of \$0.7 million to the employees of CLONDIAG and a cash payment of \$0.5 million. The fair value of our common stock issued was determined pursuant to EITF Issue No. 99-12. As of September 30, 2006, our remaining obligation was \$0.1 million. This obligation increased our aggregate purchase price to \$24.3 million as of September 30, 2006 and resulted in additional goodwill.

The terms of the acquisition agreement also provide that, in the event the value of the shares issued in connection with the acquisition is less than 4.87 million on December 29, 2006, we will be required to pay the sellers additional cash in the amount of the shortfall. In addition, the terms of the acquisition agreement provide for \$8.9 million of contingent consideration, consisting of 224,316 shares of our common stock and approximately \$3.0 million of cash or stock in the event that four specified products are developed on CLONDIAG's platform technology during the three years following the acquisition date.

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

Cash and cash equivalents	\$ 270
Accounts receivable	295
Inventories	90
Prepaid expenses and other current assets	390
Property, plant and equipment	1,774
Goodwill	11,059
Patents	11,310
In-process research and development	4,960
Other assets	20
Accounts payable and accrued expenses	(1,317 )
Deferred tax liability	(4,524 )
	\$ 24,327

The acquired patents have been assigned estimated useful lives of 20 years and have been recorded in core technology and patents, net, in the accompanying consolidated balance sheet. We have also evaluated certain in-process research and development projects and have expensed, as in-process research and development, those projects that had not yet attained technical feasibility as of the date of the acquisition. The in-process research and development amount written off during the three and nine months ended September 30, 2006 was \$5.0 million.

The acquisition of CLONDIAG is accounted for as a purchase under SFAS No. 141. Accordingly, the operating expenses of CLONDIAG, which consist principally of research and development activities, have been included in the accompanying consolidated financial statements since the acquisition date as part of our corporate and other business segment. Goodwill generated from this acquisition is not deductible for tax purposes.

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

*(c) Pro Forma Financial Information*

The following table presents selected unaudited financial information of our company, including Binax, Inc. ( Binax ), Ischemia Technologies, Inc. ( Ischemia ), the Determine/DainaScreen assets of Abbott Laboratories rapid diagnostic business (the Determine business ), Thermo BioStar, Inc. ( BioStar ), Innogenetics Diagnostica Y Terapeutica, S.A.U. ( IDT ) and Innovacon, as if the acquisitions of these entities had occurred on January 1, 2005. Pro forma results exclude adjustments for Advanced Clinical Systems Pty Ltd ( ACS ), CLONDIAG and ABON, 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, 2005.

	<b>Three Months Ended September 30, 2006</b> <small>(in thousands, except for share amounts)</small>		<b>Nine Months Ended September 30, 2006</b> <small>(in thousands, except for share amounts)</small>	
	<b>2006</b>	<b>2005</b>	<b>2006</b>	<b>2005</b>
Pro forma net revenue	\$ 144,912	\$ 130,116	\$ 425,893	\$ 393,222
Pro forma net (loss) income	\$ (9,683 )	\$ (2,036 )	\$ (19,420 )	\$ 4,511
Pro forma net (loss) income per common share basic and diluted(1)	\$ (0.27 )	\$ (0.06 )	\$ (0.57 )	\$ 0.14

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

*(d) Restructuring Plans of Acquisitions*

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

The following table sets forth the restructuring costs and accrual balances recorded on a cash basis in connection with the restructuring activities of these acquired businesses (in thousands):

	<b>Balance at December 31, 2005</b>	<b>Amounts Paid</b>	<b>Other(1)</b>	<b>Balance at September 30, 2006</b>
BioStar	\$ 83	\$ (73 )	\$	\$ 10
Ischemia	144	(99 )		45
Ostex	768	(82 )		686
IMN	127	(40 )		87
Unipath business	1,307		112	1,419
Total restructuring costs	\$ 2,429	\$ (294 )	\$ 112	\$ 2,247

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

- (1) Represents foreign currency translation adjustment

14

---

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

During the fourth quarter of 2005, we established a restructuring plan in connection with our acquisition of BioStar and recorded restructuring costs of \$0.5 million, of which \$0.4 million related to impairment of fixed assets and \$0.1 million related to severance costs associated with a headcount reduction. The total number of employees to be involuntarily terminated was nine, of which all were terminated as of September 30, 2006. Of the costs recorded during 2005, \$10,000 remains unpaid as of September 30, 2006. Although we believe our plan and estimated exit costs are reasonable, actual spending for exit activities may differ from current estimated exit costs, which might impact the final aggregate purchase price.

In connection with our acquisition of Ischemia in March 2005, we established a restructuring plan whereby we exited the current facilities of Ischemia in Denver, Colorado and combined its activities with our existing manufacturing and distribution facilities during the third quarter of 2005. Total severance costs associated with involuntarily terminated employees were estimated to be \$1.6 million, all of which was paid as of September 30, 2006. We estimated costs to vacate the Ischemia facilities to be approximately \$135,000, of which \$90,000 has been paid as of September 30, 2006. The total number of involuntarily terminated employees was 17, of which all were terminated as of September 30, 2006.

As a result of our acquisition of Ostex, we established a restructuring plan whereby we exited the facilities of Ostex in Seattle, Washington, and combined the activities of Ostex with our existing manufacturing and distribution facilities. The total number of employees to be involuntarily terminated under the restructuring plan was 38, of which all were terminated as of September 30, 2006. Total severance costs associated with involuntarily terminated employees were \$1.6 million, all of which was paid as of September 30, 2006. Costs to vacate the Ostex facilities are \$0.5 million, of which \$0.2 million has been paid as of September 30, 2006. Additionally, the remaining costs to exit the operations, primarily facilities lease commitments, were \$1.9 million, of which \$1.5 million has been paid as of September 30, 2006. Total unpaid exit costs amounted to \$0.7 million as of September 30, 2006.

Immediately after the close of our acquisition of IMN, we reorganized the business operations to improve efficiencies and eliminate redundant activities on a company-wide basis. The restructuring affected all cost centers within the organization, but most significantly responsibilities at the sales and executive levels, as such activities were combined with our existing business operations. Also, as part of the restructuring plan, we relocated one of IMN's warehouses to a closer proximity of the manufacturing facility to improve efficiency. Of the \$1.6 million in total exit costs, which includes severance costs for 47 involuntarily terminated employees and costs to vacate the warehouse, \$1.5 million has been paid as of September 30, 2006.

As a result of the acquisition of the Unipath business from Unilever Plc in 2001, we reorganized the operations of the Unipath business for purposes of improving efficiencies and achieving economies of scale on a company-wide basis. Such reorganization affected all major cost centers at the operations in England. Additionally, most business activities of the U.S. division were merged into our existing U.S. businesses. Total exit costs, which primarily related to severance and early retirement obligations for 65 involuntarily terminated employees, were \$4.1 million. As of September 30, 2006, \$1.4 million, adjusted for foreign exchange effect, in exit costs remained unpaid.

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

**(9) Minority Interest**

On May 17, 2006, we acquired 49% of TechLab, Inc. (TechLab), a privately-held developer, manufacturer and distributor of rapid non-invasive intestinal diagnostics tests in the areas of intestinal inflammation, antibiotic-associated diarrhea and parasitology. The aggregate purchase price was \$8.8 million which consisted of 303,417 shares of our common stock with an aggregate fair value of \$8.6 million and \$0.2 million in estimated direct acquisition costs. The fair value of our common stock was determined based on the average market price of our common stock pursuant to EITF Issue No. 99-12. We account for our 49% investment in TechLab under the equity method of accounting, in accordance with APB Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock*. For the three and nine months ended September 30, 2006, we recorded \$0.3 million and \$0.4 million, respectively, in other income, which represented our minority share of TechLab's profit in the respective periods.

**(10) Restructuring Plans**

**(a) 2006 Restructuring Plans**

On May 22, 2006, we committed to a plan to cease operations at our manufacturing facility in San Diego, California and to write off certain excess manufacturing equipment at other impacted facilities. Additionally, on June 7, 2006, we committed to a plan to reorganize the sales and marketing and customer service functions in certain of our U.S. professional diagnostic companies. As a result of these restructuring plans, we recorded \$1.2 million and \$11.0 million, respectively, in restructuring charges during the three and nine months ended September 30, 2006. The \$1.2 million charge for the three months ended September 30, 2006 related to severance charges. The \$11.0 million charge for the nine months ended September 30, 2006 included \$1.9 million related to severance charges, \$6.4 million related to impairment charges on fixed assets and \$2.7 million related to an impairment charge on an intangible asset. The \$11.0 million of charges for the nine months ended September 30, 2006 consisted of \$7.6 million charged to cost of sales, \$2.9 million charged to research and development and \$0.5 million charged to general and administrative expenses, of which \$1.6 million, \$6.5 million and \$2.9 million were included in our consumer diagnostic products, professional diagnostic products and corporate and other business segments, respectively.

We expect to complete these plans during the first half of 2007. Including the charges recorded through September 30, 2006, we expect the total restructuring charge related to these plans to be approximately \$13.3 million, with additional charges of \$1.3 million relating to severance and \$1.0 million relating to facility exit and closure costs. The total number of employees to be involuntarily terminated under these plans is 157, of which 10 have been terminated as of September 30, 2006. As of September 30, 2006, substantially all severance and facility exit costs remain unpaid.

**(b) 2005 Restructuring Plan**

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

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

consisted of \$0.7 million charged to cost of goods sold, \$0.4 million charged to general and administrative and \$4.3 million in gains recorded to other expense. Of the net restructuring gain of \$3.2 million included in our net loss for the nine months ended September 30, 2006, the \$1.1 million loss and the \$4.3 million gain were included in our consumer diagnostic products and corporate and other business segments, respectively. Additionally, during the three and six months ended June 30, 2006, we recorded a \$1.3 million gain on the sale of our CDIL facility in Ireland which has been recorded in loss on dispositions, net in our consolidated statements of operations and is included in our corporate and other business segment for these periods.

Net restructuring charges since the commitment date consist of \$2.6 million related to severance, early retirement and outplacement services, \$2.4 million related to impairment of fixed assets and inventory and \$1.2 million related to facility closing costs, offset by \$4.3 million related to net foreign exchange gains relating primarily to this plan of termination and a \$1.4 million gain on the sale of the manufacturing facility. Of the total \$6.2 million restructuring charges recorded in operating income, \$5.9 million and \$0.3 million were included in our consumer diagnostic products and professional diagnostic products business segments, respectively. The \$4.3 million and \$1.4 million gains are recorded as other income in our accompanying consolidated statement of operations and are included in our corporate and other business segment. The plan of termination is substantially complete as of September 30, 2006 and all 113 employees under this plan have been involuntarily terminated. All costs related to severance, early retirement, outplacement services and facility closing costs have been substantially paid as of September 30, 2006.

**(11) Loss on Dispositions**

During the nine months ended September 30, 2006, we recorded a net loss on dispositions of \$3.2 million. Included in this net loss is a \$4.6 million charge associated with management's decision to dispose of our Scandinavian Micro Biodevices ApS ( SMB ) research operation, of which \$2.0 million is related to impaired assets, primarily goodwill associated with SMB, and a \$2.6 million estimated loss on the sale of SMB. We expect the sale of this operation to be completed in the fourth quarter of 2006. The net loss on dispositions also includes an offsetting \$1.4 million gain on the sale of an idle manufacturing facility in Galway, Ireland, as a result of our 2005 restructuring plan. The net loss on dispositions of \$3.2 million is included in our corporate and other business segment for this period.

**(12) Co-Development Arrangement**

On February 25, 2005, we entered into a co-development agreement with ITI Scotland Limited ( ITI ), whereby ITI agreed to provide us with £30.0 million over three years to partially fund research and development programs focused on identifying novel biomarkers and near-patient and home-use tests for cardiovascular and other diseases ( the programs ). We agreed to invest £37.5 million in the programs over three years from the date of the agreement. Through our subsidiary, Stirling Medical Innovations Limited ( Stirling ), we established a new research center in Stirling, Scotland, where we consolidated many of our existing cardiology programs and will ultimately commercialize products arising from the programs. ITI and Stirling will have exclusive rights to the developed technology in their respective fields of use. As of September 30, 2006, we had received approximately \$36.0 million (£20.0 million) in funding from ITI. As qualified expenditures are made under the co-development arrangement, we recognize the fee earned during the period as a reduction of our related expenses, subject to certain limitations. For the three and nine months ended September 30, 2006, we recognized \$4.7 million and \$13.6 million of

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

reimbursements, respectively, of which \$4.3 million and \$12.2 million, respectively, offset our research and development spending and \$0.4 million and \$1.4 million, respectively, reduced our general, administrative and marketing spending incurred by Stirling. For the three and nine months ended September 30, 2005, we recognized \$4.3 million and \$13.7 million of reimbursements, respectively, of which \$3.8 million and \$12.6 million, respectively, offset our research and development spending and \$0.5 million and \$1.1 million, respectively, reduced our general, administrative and marketing spending incurred by Stirling. Funds received from ITI in excess of amounts earned are included in accrued expenses and other current liabilities in our accompanying consolidated balance sheet, the balance of which was \$4.7 million as of September 30, 2006.

**(13) Senior Credit Facility**

As of December 31, 2005, \$89.0 million of borrowings were outstanding under our senior credit facility. On February 8 and 9, 2006, we sold an aggregate 3,400,000 shares of our common stock at \$24.41 per share to funds affiliated with 14 accredited institutional investors in a private placement. Proceeds from the private placement were approximately \$79.3 million, net of issuance costs of \$3.7 million. Of this amount, we repaid principal and interest outstanding under our senior credit facility of \$74.1 million, with the remainder of the net proceeds retained for general corporate purposes. On February 27, 2006, we borrowed \$13.0 million under our European revolving line of credit to fund our acquisition of CLONDIAG.

On March 31, 2006, we entered into an amendment to our third amended and restated credit agreement. The amendment increased the total amount of credit available to us under the credit agreement to \$155.0 million, from \$100.0 million, consisting of a new \$45.0 million U.S. term loan, a \$40.0 million U.S. revolving line of credit, reduced from \$60.0 million under the credit agreement prior to the amendment, and a \$70.0 million European revolving line of credit, increased from \$40.0 million under the credit agreement prior to the amendment. On March 31, 2006, in connection with our acquisition of Innovacon, we incurred \$58.0 million in indebtedness under the credit agreement when we received the proceeds of the entire U.S. term loan and drew an additional \$13.0 million under the U.S. revolving line of credit. On May 12, 2006, in the connection with the acquisition of ABON, we drew \$13.0 million under the U.S. revolving line of credit.

On August 23, 2006, we sold an aggregate 5,000,000 shares of our common stock at \$30.25 per share to funds affiliated with 17 accredited institutional investors in a private placement. Proceeds from the private placement were approximately \$145.5 million, net of issuance costs of \$5.7 million. Of this amount, we repaid principal outstanding on our revolving lines of credit under our senior credit facility of \$54.0 million. Our aggregate indebtedness under the amended credit agreement was \$45.0 million as of September 30, 2006.

We will begin repaying the U.S. term loan in seven consecutive quarterly installments in October 2006, in an amount of \$112,500, which is equal to 0.25% of the aggregate \$45.0 million of U.S. term loan commitments, with the final installment due on March 31, 2008 in the amount of the remaining principal balance of the U.S. term loan. We may repay any existing or future borrowings under the revolving lines of credit at any time, but no later than March 31, 2008. We are required to make mandatory prepayments in various amounts under the credit facilities if we sell assets not in the ordinary course of

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

business above certain thresholds, issue stock or sell equity securities, issue subordinated debt or have excess cash flow.

Borrowings under the revolving lines of credit and term loan bear interest at either (i) the London Interbank Offered Rate ( LIBOR ), as defined in the agreement, plus applicable margins or, at our option, (ii) a floating index rate ( Index Rate ), as defined in the agreement, plus applicable margins. Applicable margins, if we choose to use the LIBOR or the Index Rate, can range from 2.75% to 3.75% or 1.50% to 2.50%, respectively, for our revolving lines of credit depending on the quarterly adjustments that are based on our consolidated financial performance and 4.00% or 2.75%, respectively, on our term loan. For the three and nine months ended September 30, 2006, we recorded interest expense, including amortization of deferred financing costs, under these senior credit facilities in the aggregate amount of \$2.7 million and \$6.9 million, respectively. For the three and nine months ended September 30, 2005, we recorded interest expense, including amortization of deferred financing costs, under these senior credit facilities in the aggregate amount of \$1.2 million and \$2.6 million, respectively. As of September 30, 2006, accrued interest related to the senior credit facility amounted to \$0.3 million.

Borrowings under the senior credit facility remain secured by the stock of certain of our U.S. and foreign subsidiaries, substantially all of our intellectual property rights, substantially all of the assets of our businesses in the U.S. and a significant portion of the assets of our businesses outside the U.S.

In addition, on September 8, 2006, in connection with the August 2006 equity offering mentioned above, we repaid the 10% Subordinated Notes which were due to mature on September 20, 2008. The total payment aggregated \$20.8 million, which represented the principal balance outstanding plus accrued and unpaid interest, as well as a prepayment penalty of \$0.4 million. The prepayment penalty, along with the remaining unamortized deferred financing cost and unamortized original interest discount write-offs, aggregating \$0.9 million, was charged to interest expense for the three and nine months ended September 30, 2006.

#### **(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, 2006</b>	<b>2005</b>	<b>Nine Months Ended September 30, 2006</b>	<b>2005</b>
Service cost	\$ 64	\$ 64	\$ 198	\$ 198
Interest cost	144	145	420	448
Expected return on plan assets	(120 )	(86 )	(349 )	(265 )
Realized gains	83	11	240	33
<b>Net periodic benefit costs</b>	<b>\$ 107</b>	<b>\$ 134</b>	<b>\$ 311</b>	<b>\$ 414</b>

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

**(15) Financial Information by Segment**

Under SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision-making group, in deciding how to allocate resources and in assessing performance. Our chief operating decision-making group is composed of the chief executive officer and members of senior management. Our reportable operating segments are Consumer Diagnostic Products, Vitamins and Nutritional Supplements, Professional Diagnostic Products and Corporate and Other. Included in the operating loss of Corporate and Other are non-allocable corporate expenditures and expenses related to our research and development activities in the area of cardiology for the three and nine months ended September 30, 2006, the latter of which amounted to \$9.9 million, net of the ITI funding of \$4.3 million (Note 12) and \$22.1 million, net of \$12.2 million of the ITI funding, respectively, and \$5.0 million, net of the ITI funding of \$3.8 million, and \$11.2 million, net of \$12.6 million of the ITI funding, respectively, for the three and nine months ended September 30, 2005, respectively. Also included in the operating loss of Corporate and Other for the three and nine months ended September 30, 2006 are a net loss on certain dispositions (Note 11) and \$2.6 million related to the write-off of certain cardiology related fixed assets impacted by our restructuring plans (Note 10). Total assets in the area of cardiology, which are included in Corporate and Other in the table below, amounted to \$52.4 million at September 30, 2006 and \$41.2 million at December 31, 2005.

We evaluate performance of our operating segments based on net revenue and operating income (loss). Segment information for the three and nine months ended September 30, 2006 and 2005 is as follows (in thousands):

	Consumer Diagnostic Products	Vitamins and Nutritional Supplements	Professional Diagnostic Products	Corporate and Other	Total
<b><i>Three Months Ended September 30, 2006</i></b>					
Net revenue from external customers	\$ 45,350	\$ 18,462	\$ 81,100	\$ (16,096 )	\$ 144,912
Operating income (loss)	\$ 6,373	\$ (1,174 )	\$ 11,941	\$ (16,096 )	\$ 1,044
<b><i>Three Months Ended September 30, 2005</i></b>					
Net revenue from external customers	\$ 40,680	\$ 19,395	\$ 46,219	\$ (7,016 )	\$ 106,294
Operating income (loss)	\$ 6,068	\$ (740 )	\$ 1,266	\$ (7,016 )	\$ (422 )
<b><i>Nine Months Ended September 30, 2006</i></b>					
Net revenue from external customers	\$ 134,196	\$ 59,559	\$ 218,691	\$ (45,654 )	\$ 412,446
Operating income (loss)	\$ 23,234	\$ (2,223 )	\$ 22,494	\$ (2,149 )	\$ (2,149 )
<b><i>Nine Months Ended September 30, 2005</i></b>					
Net revenue from external customers	\$ 126,895	\$ 55,234	\$ 118,247	\$ 109	\$ 300,485
Operating income (loss)	\$ 19,112	\$ (3,891 )	\$ (4,324 )	\$ (22,061 )	\$ (11,164 )
<b><i>Assets:</i></b>					
As of September 30, 2006	\$ 310,318	\$ 55,036	\$ 620,529	\$ 82,183	\$ 1,068,066
As of December 31, 2005	\$ 253,063	\$ 52,967	\$ 434,796	\$ 50,340	\$ 791,166

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

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

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

As of September 30, 2006, we had outstanding material contingent contractual obligations related to our acquisitions of Binax and CLONDIAG. With respect to Binax, the terms of the acquisition agreement provide for \$11.0 million of contingent cash consideration payable to the Binax shareholders upon the successful completion of certain new product developments during the five years following the acquisition. With respect to the acquisition of CLONDIAG, in the event that the value of the 218,502 shares of our common stock issued in connection with the acquisition is less than 4.87 million on December 29, 2006, we will be required to pay the sellers additional cash in the amount of the shortfall. In addition, the terms of the acquisition agreement provide for \$8.9 million of contingent consideration, consisting of 224,316 shares of our common stock and approximately \$3.0 million of cash or stock in the event that four specified products are developed on CLONDIAG's platform technology during the three years following the acquisition date.

**(17) Recent Accounting Pronouncements**

*Recently Issued Standards*

In February 2006, the Financial Accounting Standards Board ( FASB ) issued Statement SFAS No. 155, *Accounting for Certain Hybrid Financial Instruments*, which amends SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* and SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*. SFAS No. 155 simplifies the accounting for certain derivatives embedded in other financial instruments by allowing them to be accounted for as a whole if the holder elects to account for the whole instrument on a fair value basis. SFAS No. 155 also clarifies and amends certain other provisions of SFAS No. 133 and SFAS No. 140. SFAS No. 155 is effective for all financial instruments acquired, issued or subject to a remeasurement event occurring in fiscal years beginning after September 15, 2006. Earlier adoption is permitted, provided we have not yet issued financial statements, including for interim periods, for that fiscal year. We do not expect the adoption of SFAS No. 155 to have a material impact on our financial position, results of operations or cash flows.

In June 2006, the FASB ratified the consensus on EITF Issue No. 06-03, *How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement*. The scope of EITF Issue No. 06-03 includes any tax assessed by a governmental authority that is directly imposed on a revenue-producing transaction between a seller and a customer and may include, but is not limited to, sales, use, value added, Universal Service Fund ( USF ) contributions and some excise taxes. The Task Force affirmed its conclusion that entities should present these taxes in the income statement on either a gross or a net basis, based on their accounting policy, which should be disclosed pursuant to APB Opinion No. 22, *Disclosure of Accounting Policies*. If such taxes are significant, and are presented on a gross

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

basis, the amounts of those taxes should be disclosed. The consensus on EITF Issue No. 06-03 will be effective for interim and annual reporting periods beginning after December 15, 2006. We are currently evaluating the impact of EITF Issue No. 06-03. Should we need to change the manner in which we record gross receipts, it is not expected that the change would have a material impact on total operating revenue and expenses and operating income and net income would not be affected.

In June 2006, the FASB issued FASB Interpretation No. ( FIN ) 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109*. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*. FIN 48 prescribes a recognition threshold and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 is effective for fiscal years beginning after December 15, 2006. We are currently evaluating the impact of the adoption of FIN 48 on our financial statements, but it is not expected to be material.

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

In September 2006, the FASB issued SFAS No. 158, *Employers Accounting for Defined Benefit Pension and Other Postretirement Plan An Amendment of FASB Statements No. 87, 88, 106 and 132(R)*. SFAS No. 158 requires an employer to recognize the overfunded or underfunded status of a defined benefit postretirement plan (other than a multiemployer plan) as an asset or liability in its statement of financial position and to recognize changes in that funded status in the year in which the changes occur through other comprehensive income. SFAS No. 158 also requires the measurement of defined benefit plan assets and obligations as of the fiscal year end, in addition to footnote disclosures. As our common stock is a publicly traded equity security, we are required to recognize the funded status of defined benefit pension plans (we do not have other postretirement benefit plans) and to provide the required footnote disclosures, as of the end of this fiscal year ending December 31, 2006. We will adopt SFAS No. 158 on January 1, 2007.

In September 2006, the SEC issued SAB No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, to provide guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. Under SAB No. 108, companies should evaluate a misstatement based on its impact on the current year income statement, as well as the cumulative effect of correcting such misstatements that existed in prior years existing in the current year's ending balance sheet. SAB No. 108 is effective for fiscal years ending after November 15, 2006. We have not determined the effect the adoption of SAB No. 108 will have on our financial position, results of operations or cash flows.

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

*Recently Adopted Standards*

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs an Amendment of ARB No. 43, Chapter 4*. SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted materials (spoilage). In addition, this statement requires that allocation of fixed production overheads to the costs of conversion be based on normal capacity of production facilities. As required by SFAS No. 151, we adopted this new accounting standard on January 1, 2006. The adoption of SFAS No. 151 did not have a material impact on our financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123-R, *Share-Based Payment*, which addresses the accounting for transactions in which a company receives employee services in exchange for (a) equity instruments of the company or (b) liabilities that are based on the fair value of the company's equity instruments or that may be settled by the issuance of such equity instruments. Under the original guidance of SFAS No. 123-R, we were to adopt the statement's provisions for the interim period beginning after June 15, 2005. However, in April 2005, as a result of an action by the Securities and Exchange Commission, companies were allowed to adopt the provisions of SFAS No. 123-R at the beginning of their fiscal year that begins after June 15, 2005. Consequently, we adopted SFAS No. 123-R on January 1, 2006. See Note 4 for further discussion.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections*, which replaces APB Opinion No. 20, *Accounting Changes*, and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*. The statement requires a voluntary change in accounting principle be applied retrospectively to all prior period financial statements so that those financial statements are presented as if the current accounting principle had always been applied. APB Opinion No. 20 previously required most voluntary changes in accounting principle to be recognized by including in net income of the period of change the cumulative effect of changing to the new accounting principle. In addition, SFAS No. 154 carries forward, without change, the guidance contained in APB Opinion No. 20 for reporting a correction of an error in previously issued financial statements and a change in accounting estimate. SFAS No. 154 was effective for accounting changes and corrections of errors made after January 1, 2006. The adoption of SFAS No. 154 had no impact on our financial statements.

**(18) Related Party Transaction**

On June 20, 2006, we issued 25,000 shares of our common stock as consideration for the acquisition of all of the capital stock of Innovative Medical Devices BVBA. The seller of the capital stock of Innovative Medical Devices BVBA is the spouse of the President of our Consumer Diagnostics business unit.

On August 15, 2006, Ron Zwanziger, our Chairman, Chief Executive Officer and President, paid the Company \$11.2 million in full satisfaction of his obligations to the Company, including principal and accrued interest, under a previously disclosed, five-year promissory note dated August 16, 2001. The promissory note was provided to the Company by Mr. Zwanziger in connection with his purchase of 1,168,191 shares of the Company's common stock in August, 2001.

**(19) Guarantor Financial Information**

We issued \$150.0 million in senior subordinated notes (the "Bonds") to qualified institutional buyers in reliance on Rule 144A under the Securities Act of 1933, as amended (the "Securities Act"), and outside the United States in compliance with Regulation S of the Securities Act. Our payment obligations under

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

the Bonds are currently guaranteed by all of our domestic subsidiaries (the **Guarantor Subsidiaries** ). The guarantee is full and unconditional. Separate financial statements of the **Guarantor Subsidiaries** are not presented because we have determined that they would not be material to investors in the Bonds. The following supplemental financial information sets forth, on a consolidating basis, the statements of operations and cash flows for the three and nine months ended September 30, 2006 and 2005 and the balance sheets as of September 30, 2006 and December 31, 2005 for our company (the **Issuer** ), the **Guarantor Subsidiaries** and our other subsidiaries (the **Non-Guarantor Subsidiaries** ). The supplemental financial information reflects our investments and the **Guarantor Subsidiaries** investments in the **Guarantor** and **Non-Guarantor Subsidiaries** using the equity method of accounting.

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

24

---

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**  
**CONSOLIDATING STATEMENT OF OPERATIONS**  
**For the Three Months Ended September 30, 2006**  
**(unaudited)**  
**(in thousands)**

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

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non-Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
Net product sales	\$ 5,719	\$ 87,219	\$ 67,554	\$ (19,596 )	\$ 140,896
License and royalty revenue		35	3,981		4,016
<b>Net revenue</b>	<b>5,719</b>	<b>87,254</b>	<b>71,535</b>	<b>(19,596 )</b>	<b>144,912</b>
Cost of sales	6,869	58,729	39,372	(21,203 )	83,767
<b>Gross (loss) profit</b>	<b>(1,150 )</b>	<b>28,525</b>	<b>32,163</b>	<b>1,607</b>	<b>61,145</b>
Operating expenses:					
Research and development	787	1,901	13,337		16,025
Sales and marketing	1,522	12,944	11,520		25,986
General and administrative	5,209	5,093	7,788		18,090
Loss on dispositions, net					
<b>Operating (loss) income</b>	<b>(8,668 )</b>	<b>8,587</b>	<b>(482 )</b>	<b>1,607</b>	<b>1,044</b>
Equity in earnings of subsidiaries, net of tax		2,226		(2,226 )	
Interest expense, including amortization of original issue discounts and write-off of deferred financing costs	(5,266 )	(1,881 )	(4,973 )	3,927	(8,193 )
Other income (expense), net	2,423	596	32	(3,964 )	(913 )
<b>(Loss) income before provision for income taxes</b>	<b>(9,285 )</b>	<b>7,302</b>	<b>(5,423 )</b>	<b>(656 )</b>	<b>(8,062 )</b>
Provision for income taxes	398	660	563		1,621
<b>Net (loss) income</b>	<b>\$ (9,683 )</b>	<b>\$ 6,642</b>	<b>\$ (5,986 )</b>	<b>\$ (656 )</b>	<b>\$ (9,683 )</b>

25

---

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**  
**CONSOLIDATING STATEMENT OF OPERATIONS**  
**For the Nine Months Ended September 30, 2006**  
**(unaudited)**  
**(in thousands)**

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non-Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
Net product sales	\$ 17,512	\$ 243,518	\$ 192,157	\$ (52,941 )	\$ 400,246
License and royalty revenue		188	12,012		12,200
<b>Net revenue</b>	<b>17,512</b>	<b>243,706</b>	<b>204,169</b>	<b>(52,941 )</b>	<b>412,446</b>
Cost of sales	20,508	173,367	111,309	(54,633 )	250,551
<b>Gross (loss) profit</b>	<b>(2,996 )</b>	<b>70,339</b>	<b>92,860</b>	<b>1,692</b>	<b>161,895</b>
Operating expenses:					
Research and development	2,185	5,846	31,718		39,749
Sales and marketing	4,360	35,022	30,116		69,498
General and administrative	15,596	14,358	21,652		51,606
Loss on dispositions, net			3,191		3,191
<b>Operating (loss) income</b>	<b>(25,137 )</b>	<b>15,113</b>	<b>6,183</b>	<b>1,692</b>	<b>(2,149 )</b>
Equity in earnings of subsidiaries, net of tax		9,596		(9,596 )	
Interest expense, including amortization of original issue discounts and write-off of deferred financing costs	(13,427 )	(4,504 )	(14,439 )	11,574	(20,796 )
Other income (expense), net	7,347	4,354	3,954	(11,695 )	3,960
<b>(Loss) income before provision for income taxes</b>	<b>(21,621 )</b>	<b>14,963</b>	<b>(4,302 )</b>	<b>(8,025 )</b>	<b>(18,985 )</b>
Provision for income taxes	1,248	1,703	933		3,884
<b>Net (loss) income</b>	<b>\$ (22,869 )</b>	<b>\$ 13,260</b>	<b>\$ (5,235 )</b>	<b>\$ (8,025 )</b>	<b>\$ (22,869 )</b>

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**  
**CONSOLIDATING STATEMENT OF OPERATIONS**  
**For the Three Months Ended September 30, 2005**  
**(unaudited)**  
**(in thousands)**

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non-Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
Net product sales	\$ 6,228	\$ 57,284	\$ 54,280	\$ (15,984 )	\$ 101,808
License and royalty revenue		71	4,415		4,486
<b>Net revenue</b>	<b>6,228</b>	<b>57,355</b>	<b>58,695</b>	<b>(15,984 )</b>	<b>106,294</b>
Cost of sales	6,315	43,568	31,230	(14,454 )	66,659
<b>Gross (loss) profit</b>	<b>(87 )</b>	<b>13,787</b>	<b>27,465</b>	<b>(1,530 )</b>	<b>39,635</b>
Operating expenses:					
Research and development	316	1,570	6,110		7,996
Sales and marketing	712	8,669	8,279		17,660
General and administrative	3,523	3,880	6,998		14,401
<b>Operating (loss) income</b>	<b>(4,638 )</b>	<b>(332 )</b>	<b>6,078</b>	<b>(1,530 )</b>	<b>(422 )</b>
Equity in earnings of subsidiaries, net of tax				1,343	
Interest expense, including amortization of original issue discounts and write-off of deferred financing costs	(4,082 )	(714 )	(3,865 )	3,204	(5,457 )
Other income (expense), net	3,663	138	(241 )	(3,265 )	295
<b>(Loss) income before provision for income taxes</b>	<b>(6,400 )</b>	<b>(908 )</b>	<b>1,972</b>	<b>(248 )</b>	<b>(5,584 )</b>
Provision for income taxes	172	555	221	40	988
<b>Net (loss) income</b>	<b>\$ (6,572 )</b>	<b>\$ (1,463 )</b>	<b>\$ 1,751</b>	<b>\$ (288 )</b>	<b>\$ (6,572 )</b>

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**  
**CONSOLIDATING STATEMENT OF OPERATIONS**  
**For the Nine Months Ended September 30, 2005**  
**(unaudited)**  
**(in thousands)**

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non-Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
Net product sales	\$ 18,204	\$ 167,180	\$ 148,358	\$ (44,462 )	\$ 289,280
License and royalty revenue		197	11,008		11,205
<b>Net revenue</b>	<b>18,204</b>	<b>167,377</b>	<b>159,366</b>	<b>(44,462 )</b>	<b>300,485</b>
Cost of sales	18,700	135,932	84,435	(45,119 )	193,948
<b>Gross (loss) profit</b>	<b>(496 )</b>	<b>31,445</b>	<b>74,931</b>	<b>657</b>	<b>106,537</b>
Operating expenses:					
Research and development	1,085	4,187	15,315		20,587
Sales and marketing	1,964	24,781	25,611		52,356
General and administrative	9,972	13,097	21,689		44,758
<b>Operating (loss) income</b>	<b>(13,517 )</b>	<b>(10,620 )</b>	<b>12,316</b>	<b>657</b>	<b>(11,164 )</b>
Equity in earnings of subsidiaries, net of tax		13,310		(13,310 )	
Interest expense, including amortization of original issue discounts and write-off of deferred financing costs	(12,407 )	(1,525 )	(6,713 )	5,215	(15,430 )
Other income (expense) net	1,101	6,278	17,915	(5,215 )	20,079
<b>(Loss) income before provision for income taxes</b>	<b>(11,513 )</b>	<b>(5,867 )</b>	<b>23,518</b>	<b>(12,653 )</b>	<b>(6,515 )</b>
Provision for income taxes	357	1,691	3,307		5,355
<b>Net (loss) income</b>	<b>\$ (11,870 )</b>	<b>\$ (7,558 )</b>	<b>\$ 20,211</b>	<b>\$ (12,653 )</b>	<b>\$ (11,870 )</b>

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**  
**CONSOLIDATING BALANCE SHEET**  
**September 30, 2006**  
**(unaudited)**  
**(in thousands)**

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non-Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
<b>ASSETS</b>					
<b>Current Assets:</b>					
Cash and cash equivalents	\$ 16,416	\$ 22,841	\$ 35,315	\$	\$ 74,572
Accounts receivable, net of allowances	2,861	60,643	45,692		109,196
Inventories, net	6,262	45,136	40,137	(4,529 )	87,006
Deferred tax assets		1	844		845
Prepaid expenses and other current assets	1,561	2,950	12,151		16,662
Intercompany receivables	44,704	38,624	6,116	(89,444 )	
<b>Total current assets</b>	<b>71,804</b>	<b>170,195</b>	<b>140,255</b>	<b>(93,973 )</b>	<b>288,281</b>
Property, plant and equipment, net	2,279	26,094	52,183		80,556
Goodwill	175,803	109,116	155,105		440,024
Other intangible assets with indefinite lives		21,120	46,360		67,480
Core technology and patents, net	18,938	13,751	41,596		74,285
Other intangible assets, net	35,815	32,228	25,132		93,175
Deferred financing costs, net, and other non-current assets	5,304	2,297	4,652		12,253
Investment in subsidiaries and other investments	367,829	(902 )	105	(355,823 )	11,209
Deferred tax assets	380	(1 )	424		803
Intercompany notes receivable	224,911	68,268	(2 )	(293,177 )	
<b>Total assets</b>	<b>\$ 903,063</b>	<b>\$ 442,166</b>	<b>\$ 465,810</b>	<b>\$ (742,973 )</b>	<b>\$ 1,068,066</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>					
<b>Current liabilities:</b>					
Current portion of long-term debt	\$	\$ 563	\$ 1,205	\$	\$ 1,768
Current portion of capital lease obligations		539	32		571
Accounts payable	2,565	39,843	20,679		63,087
Accrued expenses and other current liabilities	19,131	20,764	35,338		75,233
Intercompany payables	32,175	28,770	28,500	(89,445 )	
<b>Total current liabilities</b>	<b>53,871</b>	<b>90,479</b>	<b>85,754</b>	<b>(89,445 )</b>	<b>140,659</b>
<b>Long-term liabilities:</b>					
Long-term debt, net of current portion	150,000	44,437	5,761		200,198
Capital lease obligations, net of current portion		502	46		548
Deferred tax liabilities	4,455	7,604	13,915	128	26,102
Other long-term liabilities		298	5,524		5,822
Intercompany notes payable		85,982	207,196	(293,178 )	
<b>Total long-term liabilities</b>	<b>154,455</b>	<b>138,823</b>	<b>232,442</b>	<b>(293,050 )</b>	<b>232,670</b>
<b>Stockholders equity</b>	<b>694,737</b>	<b>212,864</b>	<b>147,614</b>	<b>(360,478 )</b>	<b>694,737</b>
<b>Total liabilities and stockholders equity</b>	<b>\$ 903,063</b>	<b>\$ 442,166</b>	<b>\$ 465,810</b>	<b>\$ (742,973 )</b>	<b>\$ 1,068,066</b>

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES****CONSOLIDATING BALANCE SHEET****December 31, 2005****(unaudited)****(in thousands)**

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non-Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
<b>ASSETS</b>					
<b>Current Assets:</b>					
Cash and cash equivalents	\$ 1,196	\$ 8,080	\$ 24,994	\$	\$ 34,270
Accounts receivable, net of allowances	2,344	34,834	33,298		70,476
Inventories, net	7,518	42,794	26,997	(6,100 )	71,209
Deferred tax assets			844		844
Prepaid expenses and other current assets	2,228	2,720	12,586		17,534
Intercompany receivables	38,919	34,346	19,974	(93,239 )	
<b>Total current assets</b>	<b>52,205</b>	<b>122,774</b>	<b>118,693</b>	<b>(99,339 )</b>	<b>194,333</b>
Property, plant and equipment, net	2,632	31,164	38,415		72,211
Goodwill	72,787	109,637	139,786		322,210
Other intangible assets with indefinite lives	8,700	12,420	42,622		63,742
Core technology and patents, net	28,269	5,556	30,225		64,050
Other intangible assets, net	20,321	18,429	21,739		60,489
Deferred financing costs, net, and other non-current assets	6,696	2,051	4,266		13,013
Investment in subsidiaries and other investments	297,607	(866 )	160	(296,445 )	456
Deferred tax assets			662		662
Intercompany notes receivable	130,001	43,066		(173,067 )	
<b>Total assets</b>	<b>\$ 619,218</b>	<b>\$ 344,231</b>	<b>\$ 396,568</b>	<b>\$ (568,851 )</b>	<b>\$ 791,166</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>					
<b>Current liabilities:</b>					
Current portion of long-term debt	\$	\$	\$ 2,367	\$	\$ 2,367
Current portion of capital lease obligations		508	34		542
Accounts payable	1,549	25,438	15,168		42,155
Accrued expenses and other current liabilities	12,935	22,939	28,872		64,746
Intercompany payables	34,070	31,357	27,812	(93,239 )	
<b>Total current liabilities</b>	<b>48,554</b>	<b>80,242</b>	<b>74,253</b>	<b>(93,239 )</b>	<b>109,810</b>
<b>Long-term liabilities:</b>					
Long-term debt, net of current portion	169,456	60,000	29,161		258,617
Capital lease obligations, net of current portion		914	64		978
Deferred tax liabilities	3,900	5,964	8,889	128	18,881
Other long-term liabilities		278	5,294		5,572
Intercompany notes payable		42,331	130,736	(173,067 )	
<b>Total long-term liabilities</b>	<b>173,356</b>	<b>109,487</b>	<b>174,144</b>	<b>(172,939 )</b>	<b>284,048</b>
<b>Stockholders equity</b>	<b>397,308</b>	<b>154,502</b>	<b>148,171</b>	<b>(302,673 )</b>	<b>397,308</b>
<b>Total liabilities and stockholders equity</b>	<b>\$ 619,218</b>	<b>\$ 344,231</b>	<b>\$ 396,568</b>	<b>\$ (568,851 )</b>	<b>\$ 791,166</b>

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**  
**CONSOLIDATING STATEMENT OF CASH FLOWS**  
**For the Nine Months Ended September 30, 2006**  
**(unaudited)**  
**(in thousands)**

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
<b>Cash Flows from Operating Activities:</b>					
Net (loss) income	\$ (22,869 )	\$ 13,260	\$ (5,235 )	\$ (8,025 )	\$ (22,869 )
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:					
Equity in earnings of subsidiaries, net of tax	(9,596 )			9,596	
Interest expense related to amortization of original issue discount and write-off of deferred financing costs	1,751	816	685		3,252
Non-cash income related to currency	(217 )				(217 )
Non-cash stock-based compensation expense	3,872				3,872
Charge for in-process research and development			4,960		4,960
Depreciation and amortization	7,285	9,423	12,505		29,213
Deferred income taxes	175	1,694	(9 )		1,860
Impairment of long-lived assets		5,216	3,927		9,143
Other non-cash items	(235 )	9	(1,291 )		(1,517 )
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net	(517 )	(16,030 )	(8,472 )		(25,019 )
Inventories	1,256	(92 )	(8,200 )	(1,571 )	(8,607 )
Prepaid expenses and other current assets	667	(33 )	2,433		3,067
Accounts payable	2,808	11,260	2,134		16,202
Accrued expenses and other current liabilities	(3,279 )	(3,948 )	546		(6,681 )
Other long-term liabilities		20	204		224
Intercompany payable (receivable)	(8,045 )	(2,501 )	7,968	2,578	
<b>Net cash (used in) provided by operating activities</b>	<b>(26,944 )</b>	<b>19,094</b>	<b>12,155</b>	<b>2,578</b>	<b>6,883</b>

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**  
**CONSOLIDATING STATEMENT OF CASH FLOWS (Continued)**  
**For the Nine Months Ended September 30, 2006**  
**(unaudited)**  
**(in thousands)**

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non-Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
<b>Cash Flows from Investing Activities:</b>					
Purchases of property, plant and equipment					
	(623 )	(2,866 )	(10,068 )		(13,557 )
Proceeds from sale of property, plant and equipment		15	2,202		2,217
Cash paid for acquisitions, net of cash acquired	(107,614 )	(82 )	(16,699 )		(124,395 )
Increase in other assets	(1,686 )	(16 )	(329 )		(2,031 )
<b>Net cash used in investing activities</b>	<b>(109,923 )</b>	<b>(2,949 )</b>	<b>(24,894 )</b>		<b>(137,766 )</b>
<b>Cash Flows from Financing Activities:</b>					
Cash paid for financing costs	(16 )	(1,003 )	(993 )		(2,012 )
Proceeds from issuance of common stock, net of issuance costs	231,333				231,333
Net repayment under revolving lines of credit		(15,000 )	(30,127 )		(45,127 )
Repayments of notes payable	(20,000 )		(2,614 )		(22,614 )
Principal payments of capital lease obligations		(381 )	(28 )		(409 )
Repayments of notes receivable	10,665				10,665
Intercompany notes (receivable) payable	(69,895 )	15,000	54,895		
<b>Net cash provided by (used in) financing activities</b>	<b>152,087</b>	<b>(1,384 )</b>	<b>21,133</b>		<b>171,836</b>
Foreign exchange effect on cash and cash equivalents			1,927	(2,578 )	(651 )
<b>Net increase in cash and cash equivalents</b>	<b>15,220</b>	<b>14,761</b>	<b>10,321</b>		<b>40,302</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>1,196</b>	<b>8,080</b>	<b>24,994</b>		<b>34,270</b>
<b>Cash and cash equivalents, end of period</b>	<b>\$ 16,416</b>	<b>\$ 22,841</b>	<b>\$ 35,315</b>	<b>\$</b>	<b>\$ 74,572</b>

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**  
**CONSOLIDATING STATEMENT OF CASH FLOWS**  
**For the Nine Months Ended September 30, 2005**  
**(unaudited)**  
**(in thousands)**

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non-Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
<b>Cash Flows from Operating Activities:</b>					
<b>Net (loss) income</b>					
Net (loss) income	\$ (11,870 )	\$ (7,558 )	\$ 20,211	\$ (12,653 )	\$ (11,870 )
<b>Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:</b>					
Equity in earnings of subsidiaries, net of tax	(13,310 )			13,310	
Interest expense related to amortization of original issue discount and write-off of deferred financing costs	885	448	327		1,660
Non-cash loss related to currency	212				212
Non-cash stock-based compensation expense	140				140
Depreciation and amortization	2,378	7,008	9,609		18,995
Deferred income taxes	337	1,578			1,915
Impairment of long-lived assets					
Other non-cash items	141	(13 )	(139 )		(11 )
<b>Changes in assets and liabilities, net of acquisitions:</b>					
Accounts receivable, net	(172 )	15,006	(6,354 )		8,480
Inventories	(197 )	160	(3,763 )	(657 )	(4,457 )
Prepaid expenses and other current assets	(249 )	349	(4,042 )		(3,942 )
Accounts payable	517	(23 )	3,161		3,655
Accrued expenses and other current liabilities	(2,695 )	2,372	8,292		7,969
Other long-term liabilities			(124 )		(124 )
Intercompany payable (receivable)	2,527	(683 )	(1,610 )	(234 )	
<b>Net cash (used in) provided by operating activities</b>	<b>(21,356 )</b>	<b>18,644</b>	<b>25,568</b>	<b>(234 )</b>	<b>22,622</b>

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**  
**CONSOLIDATING STATEMENT OF CASH FLOWS (Continued)**  
**For the Nine Months Ended September 30, 2005**  
**(unaudited)**  
**(in thousands)**

	<b>Issuer</b>	<b>Guarantor Subsidiaries</b>	<b>Non-Guarantor Subsidiaries</b>	<b>Eliminations</b>	<b>Consolidated</b>
<b>Cash Flows from Investing Activities:</b>					
Purchases of property, plant and equipment	(534 )	(5,558 )	(8,570 )		(14,662 )
Proceeds from sale of property, plant and equipment		81	91		172
Cash paid for acquisitions, net of cash acquired	(68,055 )	1,555	(73,181 )		(139,681 )
Increase in other assets	(29 )	(272 )	(1,074 )		(1,375 )
<b>Net cash used in investing activities</b>	<b>(68,618 )</b>	<b>(4,194 )</b>	<b>(82,734 )</b>		<b>(155,546 )</b>
<b>Cash Flows from Financing Activities:</b>					
Cash paid for financing costs	(95 )	(1,303 )	(1,250 )		(2,648 )
Proceeds from issuance of common stock, net of issuance costs	95,956				95,956
Net (repayment) borrowing under revolving lines of credit	(77 )	29,070	25,623		54,616
Repayments of notes payable			69		69
Principal payments of capital lease obligations		(353 )	(5 )		(358 )
Intercompany notes payable (receivable)	(5,000 )	(37,000 )	42,000		
<b>Net cash provided by (used in) financing activities</b>	<b>90,784</b>	<b>(9,586 )</b>	<b>66,437</b>		<b>147,635</b>
Foreign exchange effect on cash and cash equivalents		96	(1,824 )	234	(1,494 )
<b>Net increase in cash and cash equivalents</b>	<b>810</b>	<b>4,960</b>	<b>7,447</b>		<b>13,217</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>12</b>	<b>3,551</b>	<b>13,193</b>		<b>16,756</b>
<b>Cash and cash equivalents, end of period</b>	<b>\$ 822</b>	<b>\$ 8,511</b>	<b>\$ 20,640</b>	<b>\$</b>	<b>\$ 29,973</b>

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

**Financial Overview**

As a leading global manufacturer and supplier of rapid diagnostic products for consumer and professional markets, we are continually exploring new opportunities for our proprietary technologies in a variety of professional diagnostic and consumer-oriented applications, including immuno-diagnostics with a focus on women's health, cardiology and infectious disease. As part of this strategy, we are focused on opportunities, including acquisitions and strategic partnerships, aimed at expanding both our product offerings and our distribution capability in the rapid diagnostic marketplace. We are also focused on improving our margins through consolidation of certain of our manufacturing operations at lower cost facilities. In addition, we continue to seek opportunities to integrate the distribution of acquired products into our expanding distribution capabilities.

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

For the three and nine months ended September 30, 2006, we recorded net revenue of \$144.9 million and \$412.4 million, respectively, compared to \$106.3 million and \$300.5 million, respectively, for the three and nine months ended September 30, 2005. Overall revenue growth for the nine months ended September 30, 2006, adjusted for the impact of currency translation, resulted primarily from acquisitions principally in our professional diagnostics business and, to a lesser extent, organic growth. Our acquisitions in the second half of 2005 and first quarter of 2006 contributed approximately \$28.6 million of the increase.

For the three and nine months ended September 30, 2006, we incurred a net loss of \$9.7 million and \$22.9 million, respectively, compared to a net loss of \$6.6 million and \$11.9 million, respectively, for the three and nine months ended September 30, 2005. Included in the prior year nine-month period was a net favorable impact resulting from settlement of disputes and a licensing arrangement which totaled \$17.7 million, net of tax.

During the nine months ended September 30, 2006, we acquired (i) CLONDIAG chip technologies GmbH (CLONDIAG), a privately-held company located in Jena in Germany which has developed a multiplexing technology for nucleic acid and immunoassay-based diagnostics, for a preliminary aggregate purchase price of \$24.3 million, and (ii) the assets of ACON Laboratories business of researching, developing, manufacturing, marketing and selling lateral flow immunoassay and directly-related products in the United States, Canada, Europe (excluding Russia, the former Soviet Republics that are not part of the European Union, Spain, Portugal and Turkey), Israel, Australia, Japan and New Zealand (Innovacon) for a preliminary aggregate purchase price of approximately \$179.1 million. As part of the ACON transaction we acquired a newly-constructed, 300,000 square foot manufacturing facility in Hangzhou, China which is a key component of our plans to lower manufacturing costs and improve margins.

In connection with our February 2006 acquisition of CLONDIAG, we recorded a \$5.0 million charge during the third quarter of 2006 related to the write-off of in-process research and development projects that had not attained technical feasibility as of the date of the acquisition.

On May 22, 2006, we committed to a plan to cease operations at our manufacturing facility in San Diego, California and to write off certain excess manufacturing equipment at other impacted facilities. Additionally, on June 7, 2006, we committed to a plan to reorganize the sales and marketing and customer service functions in certain of our U.S. professional diagnostic companies. As a result of these restructuring plans, we recorded \$1.2 million and \$11.0 million, respectively, in restructuring charges during the three

and nine months ended September 30, 2006. We expect to complete these plans during the first half of 2007. Including the charges recorded through September 30, 2006, we expected the total restructuring charge related to these plans to be approximately \$13.3 million.

### Results of Operations

**Net Revenue.** Net revenue increased by \$38.6 million, or 36%, to \$144.9 million for the three months ended September 30, 2006 from \$106.3 million for the three months ended September 30, 2005. Net revenue increased by \$112.0 million, or 37%, to \$412.4 million for the nine months ended September 30, 2006, from \$300.5 million for the nine months ended September 30, 2005. The factors resulting in the changes in net revenue for each comparative period are discussed in the Net Product Sales, Total and by Business Segment and License and Royalty Revenue discussions which follow.

**Net Product Sales, Total and by Business Segment.** Net product sales increased by \$39.1 million, or 38%, to \$140.9 million for the three months ended September 30, 2006, from \$101.8 million for the three months ended September 30, 2005. Net product sales increased by \$111.0 million, or 38%, to \$400.2 million for the nine months ended September 30, 2006, from \$289.3 million for the nine months ended September 30, 2005. Net product sales by business segment for the three and nine months ended September 30, 2006 and 2005 are as follows (in thousands):

	Three Months Ended		% Change	Nine Months Ended		% Change
	September 30, 2006	2005		September 30, 2006	2005	
Consumer diagnostic products	\$ 43,885	\$ 38,939	13 %	\$ 129,427	\$ 122,866	5 %
Vitamins and nutritional supplements	18,462	19,395	(5 )%	59,559	55,234	8 %
Professional diagnostic products	78,549	43,474	81 %	211,260	111,180	90 %
Net product sales	\$ 140,896	\$ 101,808	38 %	\$ 400,246	\$ 289,280	38 %

Net product sales of our consumer diagnostic products increased by \$4.9 million, or 13%, comparing the three months ended September 30, 2006 to the three months ended September 30, 2005 and \$6.6 million, or 5%, comparing the nine months ended September 30, 2006 to the nine months ended September 30, 2005. Revenue from our March 2006 acquisition of Innovacon accounted for \$2.3 million and \$5.2 million of the increase during the three and nine months ended September 30, 2006, respectively.

Our vitamins and nutritional supplements product sales decreased by \$0.9 million, or 5%, comparing the three months ended September 30, 2006 to the three months ended September 30, 2005 and increased by \$4.3 million, or 8%, comparing the nine months ended September 30, 2006 to the nine months ended September 30, 2005, with increased sales of our private label nutritional supplements accounting for the majority of the growth in the nine-month comparative period.

Net product sales of our professional diagnostic products increased by \$35.1 million, or 81%, comparing the three months ended September 30, 2006 to the three months ended September 30, 2005 and increased by \$100.1 million, or 90%, comparing the nine months ended September 30, 2006 to the nine months ended September 30, 2005. Net product revenue during the three months ended September 30, 2006 increased as a result of our acquisitions of IDT in September 2005 which contributed \$2.9 million; BioStar in September 2005 which contributed \$6.5 million; CLONDIAG in February 2006 which contributed \$0.5 million and Innovacon in March 2006 which contributed \$16.4 million, for a total contribution of \$26.3 million of net product sales during the three months ended September 30, 2006. Net product revenue during the nine months ended September 30, 2006 increased primarily as a result of our acquisitions of Binax in March 2005 which contributed incremental revenue of \$8.9 million; the Determine business in June 2005 which contributed incremental revenue of \$17.1 million; IDT in September 2005 which contributed \$10.4 million; BioStar in September 2005 which contributed \$20.9 million; CLONDIAG

in February 2006 which contributed \$1.5 million and Innovacon in March 2006 which contributed \$31.5 million, for a total contribution of \$90.3 million of net product sales during the nine months ended September 30, 2006 in excess of the contribution during the nine months ended September 30, 2005.

**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 \$0.5 million, or 11%, to \$4.0 million for the three months ended September 30, 2006 from \$4.5 million for the three months ended September 30, 2005 and increased by \$1.0 million, or 9%, to \$12.2 million for the nine months ended September 30, 2006 from \$11.2 million for the nine months ended September 30, 2005.

**Gross Profit and Margin.** Gross profit increased by \$21.5 million, or 54%, to \$61.1 million for the three months ended September 30, 2006 from \$39.6 million for the three months ended September 30, 2005. Gross profit during the three months ended September 30, 2006 benefited from higher than average margins earned on revenue from our recently acquired businesses, and from favorable product mix offset by the lower royalties recognized during the quarter. Included in cost of sales for the three months ended September 30, 2006 was a restructuring charge of \$1.2 million related to the recently announced closure of our ABI operation in San Diego, California, along with the write-off of fixed assets at other facilities impacted by our restructuring plans and a \$0.1 million charge for stock-based compensation related to our January 1, 2006 adoption of Statement of Financial Accounting Standards ( SFAS ) No. 123-R, *Share-Based Payment*. Included in cost of sales for the three months ended September 30, 2005 was a \$0.6 million restructuring charge associated with our decision to close our Galway, Ireland manufacturing facility.

Gross profit increased by \$55.4 million, or 52%, to \$161.9 million for the nine months ended September 30, 2006 from \$106.5 million for the nine months ended September 30, 2005. Included in cost of sales for the nine months ended September 30, 2006 was a \$8.3 million restructuring charge related to the closures of our Galway, Ireland manufacturing facility and ABI operation in San Diego, California, along with the write-off of fixed assets at other facilities impacted by our restructuring plans and a \$0.3 million charge for stock-based compensation related to our January 1, 2006 adoption of SFAS No. 123-R. The nine months ended September 30, 2005 included \$3.5 million of restructuring charges, a \$2.4 million charge associated with a reserve established at our Wampole subsidiary for excess quantities of certain raw materials and finished goods, including certain finished goods held at distributors, but subject to right of return, and \$1.6 million charge for returns and inventory reserve related to the recall of the drugs of abuse diagnostic products.

Amortization expense of \$3.2 million and \$8.5 million was included in cost of sales during the three and nine months ended September 30, 2006, respectively. Cost of sales for the three and nine months ended September 30, 2005 included amortization expense of \$2.0 million and \$5.4 million, respectively.

Overall gross margin was 42% and 39% for the three and nine months ended September 30, 2006, respectively, compared to 37% and 35%, respectively, for the three and nine months ended September 30, 2005.

**Gross Profit from Net Product Sales by Business Segment.** Gross profit from net product sales represents total gross profit less gross profit associated with license and royalty revenue. Gross profit from net product sales increased by \$22.1 million, or 61%, to \$58.5 million for the three months ended September 30, 2006 from \$36.4 million for the three months ended September 30, 2005. Gross profit from net product sales increased by \$55.1 million, or 56%, to \$153.7 million for the nine months ended September 30, 2006 from \$98.6 million for the nine months ended September 30, 2005. Gross profit from net product sales by business segment for the three and nine months ended September 30, 2006 and 2005 are as follows (in thousands):

	Three Months Ended		% Change	Nine Months Ended		% Change
	September 30, 2006	2005		September 30, 2006	2005	
Consumer diagnostic products	\$ 22,410	\$ 18,819	19 %	\$ 63,586	\$ 58,291	9 %
Vitamins and nutritional supplements	828	1,479	(44 )%	3,842	3,406	13 %
Professional diagnostic products	35,229	16,087	119 %	86,316	36,931	134 %
Gross profit from net product sales	\$ 58,467	\$ 36,385	61 %	\$ 153,744	\$ 98,628	56 %

Gross profit from our consumer diagnostic product sales increased by \$3.6 million, or 19%, to \$22.4 million for the three months ended September 30, 2006, compared to \$18.8 million for the three months ended September 30, 2005. Gross profit from our consumer diagnostic product sales increased by \$5.3 million, or 9%, to \$63.6 million for the nine months ended September 30, 2006, compared to \$58.3 million for the nine months ended September 30, 2005. Included in the cost of sales for the three months ended September 30, 2006 was a charge of \$0.1 million for stock-based compensation related to our January 1, 2006 adoption of SFAS No. 123-R. Included in the cost of sales for the three months ended September 30, 2005 was a \$3.5 million restructuring charge associated with our decision to close our Galway, Ireland manufacturing facility during this period. Cost of sales for the nine months ended September 30, 2006 included restructuring charges totaling \$2.2 million related to the closure of our Galway, Ireland manufacturing facility and a \$0.3 million charge for stock-based compensation. During the nine months ended September 30, 2005, cost of sales included a restructuring charge of \$3.5 million, as discussed above.

As a percentage of our consumer diagnostic product sales, gross margin was 51% and 49% for the three and nine months ended September 30, 2006, respectively. Gross margin percentages for the three and nine months ended September 30, 2005 were 48% and 47%, respectively.

Gross profit from our vitamins and nutritional supplements product sales decreased \$0.7 million, or 44%, to \$0.8 million for the three months ended September 30, 2006, compared to \$1.5 million for the three months ended September 30, 2005. Gross profit from our vitamins and nutritional supplements product sales increased \$0.4 million, or 13%, to \$3.8 million for the nine months ended September 30, 2006, compared to \$3.4 million for the nine months ended September 30, 2005. The gross profit increase in the nine-month period was the result of improved factory utilization as a result of increasing revenue in our private label business during the second quarter of 2006.

As a percentage of net vitamin and nutritional supplements product sales, gross profit for our vitamins and nutritional supplements business was approximately 4% and 6% for the three and nine months ended September 30, 2006, respectively, compared to 8% and 6% for the three and nine months ended September 30, 2005, respectively.

Gross profit from our professional diagnostic product sales increased by \$19.1 million, or 119%, to \$35.2 million for the three months ended September 30, 2006, compared to \$16.1 million for the three months ended September 30, 2005. Gross profit from our professional diagnostic product sales increased by \$49.4 million, or 134%, to \$86.3 million for the nine months ended September 30, 2006, compared to

\$36.9 million for the nine months ended September 30, 2005. The increase in gross profit during the three months ended September 30, 2006 is largely attributable to the increase in product sales resulting primarily from our acquisitions of BioStar, IDT and Innovacon where higher margin products are sold. In addition to the acquisitions contributing to the gross profit improvement during the third quarter of 2006, our acquisition of Binax also contributed to the gross profit improvement during the nine months ended September 30, 2006, compared to the nine months ended September 30, 2005. Included in cost of sales for the three and nine months ended September 30, 2006 was a \$0.7 million and \$6.1 million restructuring charge, respectively, associated with our decision to close our ABI operations. Cost of sales for the nine months ended September 30, 2005 included a charge of \$2.4 million associated with a reserve established at our Wampole subsidiary for excess quantities of certain raw materials and finished goods, including certain finished goods held at distributors but subject to right of return and a \$1.6 million charge related to a recall of the drugs of abuse diagnostic products.

As a percentage of our professional diagnostic product sales, gross margin for the three and nine months ended September 30, 2006 was 45% and 41%, respectively. As a percentage of our professional diagnostic product sales, gross margin for the three and nine months ended September 30, 2005 was 37% and 33%, respectively.

**Research and Development Expense.** Research and development expense increased by \$8.0 million, or 100%, to \$16.0 million for the three months ended September 30, 2006, compared to \$8.0 million for the three months ended September 30, 2005. Research and development expense increased by \$19.2 million, or 93%, to \$39.7 million for the nine months ended September 30, 2006, compared to \$20.6 million for the nine months ended September 30, 2005. Research and development expense is reported net of \$4.3 million and \$12.2 million for the three and nine months ended September 30, 2006, respectively, received from ITI Scotland Limited ( ITI ) under our 2005 co-development agreement. ITI funding during the three and nine months ended September 30, 2005 was \$3.8 million and \$12.6 million, respectively. The increase in research and development expense for the comparative three-month periods was primarily the result of increased spending related to our cardiology research programs, \$6.2 million of additional spending related to our recent acquisitions, a \$0.3 million charge related to the write-off of fixed assets impacted by our restructuring plans and a \$0.3 million charge for stock-based compensation related to our January 1, 2006 adoption of SFAS No. 123-R. Included in the \$6.2 million of additional spending related to recent acquisitions is a \$5.0 million charge related to the write-off of in-process research and development projects that had not achieved technical feasibility as of the date of our acquisition of Clondiag. The increase for the comparative nine-month periods was primarily the result of increased spending related to our cardiology research programs, \$6.2 million of additional spending related to our recent acquisitions, a \$2.9 million charge related to the write-off of fixed assets impacted by our restructuring plans and a \$0.9 million charge for stock-based compensation related to our January 1, 2006 adoption of SFAS No. 123-R.

Amortization expense of \$1.0 million and \$2.3 million was included in research and development expense during the three and nine months ended September 30, 2006, respectively. Research and development expense for the three and nine months ended September 30, 2005 included amortization expense of \$0.5 million and \$1.6 million, respectively.

Research and development expense as a percentage of net product sales is 11% and 10% for the three and nine months ended September 30, 2006, respectively, compared to 8% and 7% for the three and nine months ended September 30, 2005, respectively.

**Sales and Marketing Expense.** Sales and marketing expense increased by \$8.3 million, or 47%, to \$26.0 million for the three months ended September 30, 2006, compared to \$17.7 million for the three months ended September 30, 2005. Sales and marketing expense increased by \$17.1 million, or 33%, to \$69.5 million for the nine months ended September 30, 2006, compared to \$52.4 million for the nine

months ended September 30, 2005. For the three and nine months ended September 30, 2006, approximately \$6.0 million and \$14.1 million, respectively, resulted from additional spending related to our acquisitions of BioStar, IDT, CLONDIAG, Innovacon, and ABON, along with Binax and the Determine business during the nine-month period. Additionally, sales and marketing for the three and nine months ended September 30, 2006 included a charge of \$0.1 million and \$0.4 million, respectively, for stock-based compensation related to our January 1, 2006 adoption of SFAS No. 123-R.

Amortization expense of \$2.1 million and \$5.3 million was included in sales and marketing expense during the three and nine months ended September 30, 2006, respectively. Sales and marketing expense for the three and nine months ended September 30, 2005 included amortization expense of \$0.6 million and \$1.7 million, respectively.

Sales and marketing expense as a percentage of net product sales was 18% and 17% for the three and nine months ended September 30, 2006, respectively, compared to 17% and 18% for the three and nine months ended September 30, 2005, respectively.

**General and Administrative Expense.** General and administrative expense increased by \$3.7 million, or 25%, to \$18.1 million for the three months ended September 30, 2006, compared to \$14.4 million for the three months ended September 30, 2005. General and administrative expense increased by \$6.8 million, or 15%, to \$51.6 million for the nine months ended September 30, 2006, compared to \$44.8 million for the nine months ended September 30, 2005. For the three and nine months ended September 30, 2006, approximately \$3.4 million and \$8.8 million, respectively, of the increase in general and administrative expense resulted from additional spending related to our acquisitions of BioStar, IDT, CLONDIAG, Innovacon and ABON, along with Binax and the Determine business during the nine-month period. Included in general and administrative expense is a \$0.8 million and a \$2.3 million charge for stock-based compensation related to our January 1, 2006 adoption of SFAS No. 123-R for the three and nine-month periods in 2006, respectively. Increases in general and administrative expenses during the three and nine months ended September 30, 2006 were partially offset by decreases in legal expenses in both periods of \$1.2 million and \$4.6 million, respectively.

Amortization expense of \$0.1 million and \$0.3 million was included in general and administrative expense during the three and nine months ended September 30, 2006, respectively. General and administrative expense for the three and nine months ended September 30, 2005 included amortization expense of \$0.1 million and \$0.3 million, respectively.

General and administrative expense as a percentage of net product sales was 13% and 13% for the three and nine months ended September 30, 2006, respectively, compared to 14% and 15% for the three and nine months ended September 30, 2005, respectively.

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

**Interest Expense.** Interest expense includes interest charges, the write-off and amortization of deferred financing costs and the write-off and amortization of non-cash discounts associated with our debt issuances. Interest expense for the three months ended September 30, 2006 increased by \$2.7 million, or 50%, to \$8.2 million from \$5.5 million for the three months ended September 30, 2005. Such increase was partially due to a higher average outstanding debt balance of \$240.0 million during the quarter, compared to \$237.0 million during the comparable quarter in 2005, as a result of borrowings to fund various

acquisitions and operations. Additionally, interest expense for the three months ended September 30, 2006 included \$1.3 million of charges related to prepayment penalties and the write-off of debt origination costs resulting from the early repayment of our \$20.0 million, 10% subordinated promissory notes on September 8, 2006.

Interest expense for the nine months ended September 30, 2006 increased by \$5.4 million, or 35%, to \$20.8 million from \$15.4 million for the nine months ended September 30, 2005. Such increase was partially due to a higher average outstanding debt balance of \$232.8 million during the nine-month period in 2006, compared to \$219.4 million during the nine-month period in 2005, as a result of borrowings to fund various acquisitions and operations. In addition to the \$1.3 million of charges incurred during the third quarter of 2006, discussed above, higher applicable interest rates on the senior credit facility during the nine months ended September 30, 2006 compared with the nine months ended September 30, 2005 and an increase in the amortization of deferred financing costs related to the debt refinancings that occurred later in fiscal year 2005 and during the first quarter of 2006 also contributed to the increase in interest expense.

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

	Three Months Ended September 30,		% Change	Nine Months Ended September 30,		% Change
	2006	2005		2006	2005	
Interest income	\$ 439	\$ 259	69 %	\$ 1,058	\$ 764	38 %
Foreign exchange gains (losses), net	(107 )	(233 )	54 %	3,236	(350 )	1,025 %
Other	(1,245 )	269	(563 )%	(334 )	19,665	(102 )%
Other income (expense), net	\$ (913 )	\$ 295	(409 )%	\$ 3,960	\$ 20,079	(80 )%

Included in other income (expense), net for the three months ended September 30, 2006 was \$1.5 million of charges related to two legal settlements during this period. In addition to the \$1.5 million in legal settlements, other income (expense), net for the nine months ended September 30, 2006 included a foreign exchange gain of \$4.3 million associated with the closure of our Galway, Ireland manufacturing operation. Included in other income (expense), net for the nine months ended September 30, 2005 was income of \$15.0 million related to the Quidel legal settlement and \$2.6 million related to the value of an option received under a licensing arrangement entered into during the second quarter of 2005, offset by a \$2.7 million charge related to a legal settlement of a nutritional segment commercial dispute arising from a distribution arrangement entered into in September 1996. In addition, other income (expense), net for the nine months ended September 30, 2005 includes an \$8.4 million gain from a legal settlement of class action suit against several raw material suppliers in our vitamins and nutritional supplements business and a \$4.3 million charge related to a legal settlement with PBM.

**Provision for Income Taxes.** Provision for income taxes was \$1.6 million and \$3.9 million for the three and nine months ended September 30, 2006, respectively, compared to \$1.0 million and \$5.4 million for the three and nine months ended September 30, 2005, respectively. The effective tax rate was (20)% for both the three and nine months ended September 30, 2006, compared to (18)% and (82)% for the three and nine months ended September 30, 2005, respectively. The income tax provision for both comparative periods is primarily related to the recognition of U.S. deferred tax liabilities for temporary differences between the book and tax basis of goodwill and certain intangible assets with indefinite lives, state income tax provision and foreign income tax provisions for various foreign subsidiaries.

**Net Loss.** We incurred a net loss of \$9.7 million, or \$0.27 per basic and diluted common share, for the three months ended September 30, 2006, compared to a net loss of \$6.6 million, or \$0.25 per basic and diluted common share, for the three months ended September 30, 2005. For the nine months ended September 30, 2006, we incurred a net loss of \$22.9 million, or \$0.70 per basic and diluted common share, compared to a net loss of \$11.9 million, or \$0.51 per basic and diluted common share, for the nine months ended September 30, 2005. The increase in net loss for the comparative three and nine months ended September 30, 2006 and 2005, primarily resulted from the various factors as discussed above. See Note 5 of the accompanying consolidated financial statements for the calculation of net income (loss) per common share.

### **Liquidity and Capital Resources**

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

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

#### *Changes in Cash Position*

As of September 30, 2006, we had cash and cash equivalents of \$74.6 million, a \$40.3 million increase from December 31, 2005. Our primary sources of cash during the nine months ended September 30, 2006, included \$231.3 million in proceeds from the issuance of our common stock, including common stock issues under employee stock option and stock purchase plans, and \$10.7 million in proceeds from the repayment of a note receivable. During the nine months ended September 30, 2006, our operating activities provided \$6.9 million of cash to fund our net loss of \$22.9 million and a \$20.8 million use of cash associated with an increase in working capital, which were offset by \$50.6 million of non-cash items. Our investing activities during the nine months ended September 30, 2006 used \$137.8 million of cash and consisted primarily of \$124.4 million of cash used for acquisitions and \$13.6 million used for capital equipment purchases, offset by a net \$0.2 million of proceeds from the sale of our Galway, Ireland facility and sales of capital equipment, along with decreases in other assets. Our non-equity financing activities, primarily borrowings under our primary senior credit facility, net of various debt repayments and financing

costs, used cash of \$70.2 million during the nine months ended September 30, 2006. Fluctuations in foreign currencies adversely impacted our cash balance by \$0.6 million during the nine months ended September 30, 2006.

*Investing Activities*

During the nine months ended September 30, 2006, we paid \$124.4 million in cash for acquisitions and transaction related costs, net of cash acquired, primarily with respect to our acquisitions of CLONDIAG, Innovacaon and ABON during this period.

On February 28, 2006, we acquired 67.45% of CLONDIAG, a privately-held company located in Jena in Germany which has developed a multiplexing technology for nucleic acid and immunoassay-based diagnostics. Pursuant to the acquisition agreement, we purchased the remaining 32.55% on August 31, 2006. The aggregate purchase price was \$23.0 million, which consisted of an initial cash payment of \$11.9 million, 218,502 shares of our common stock with an aggregate fair value of \$5.8 million and a \$5.3 million cash payment to acquire the remaining 32.55% stock ownership. Additionally, pursuant to the terms of the acquisition agreement, we assumed an obligation to settle existing employee bonus arrangement with the CLONDIAG employees totaling 1.1 million (\$1.3 million). In connection with this obligation, we issued 24,896 shares of our common stock with a fair value of \$0.7 million to the employees of CLONDIAG and a cash payment of \$0.5 million. As of September 30, 2006, our remaining obligation was \$0.1 million. This obligation increased our aggregate purchase price to \$24.3 million as of September 30, 2006 and resulted in additional goodwill.

The terms of the acquisition agreement also provide that, in the event the value of the shares issued in connection with the acquisition is less than 4.87 million on December 29, 2006, we will be required to pay the sellers additional cash in the amount of the shortfall. In addition, the terms of the acquisition agreement provide for \$8.9 million of contingent consideration, consisting of 224,316 shares of our common stock and approximately \$3.0 million of cash or stock in the event that four specified products are developed on CLONDIAG's platform technology during the three years following the acquisition date.

On March 31, 2006, we acquired the assets of ACON Laboratories business of researching, developing, manufacturing, marketing and selling lateral flow immunoassay and directly-related products in the United States, Canada, Europe (excluding Russia, the former Soviet Republics that are not part of the European Union, Spain, Portugal and Turkey), Israel, Australia, Japan and New Zealand ( Innovacaon ). The preliminary aggregate purchase price was approximately \$91.6 million which consisted of \$55.1 million in cash, 711,676 shares of our common stock with an aggregate fair value of \$19.7 million, \$6.8 million in estimated direct acquisition costs and an additional liability of \$10.0 million payable to the sellers on the deferred payment date, pursuant to the purchase agreement.

On May 15, 2006, we acquired a newly-constructed manufacturing facility in Hangzhou, China ( ABON ), pursuant to the terms of our acquisition agreement with ACON Laboratories, Inc. and its affiliates. In connection with the acquisition of the new facility, we acquired ABON BioPharm (Hangzhou) Co., Ltd ( ABON ), the direct owner of the new factory and now our subsidiary. The preliminary aggregate purchase price was approximately \$20.8 million which consisted of \$8.8 million in cash and 417,446 shares of our common stock with an aggregate fair value of \$12.0 million. In addition, pursuant to the acquisition agreement, we made an additional payment of \$4.1 million in cash as a result of the amount of cash acquired, net of indebtedness assumed, which increased the preliminary aggregate purchase price to \$24.9 million.

On August 28, 2006, pursuant to the above agreement, we paid cash of approximately \$17.5 million and issued 463,830 shares of our common stock with an aggregate fair value of \$13.3 million upon the ABON facility being fully functional for the sale of products in the United States of America. On September 1, 2006, we paid cash of approximately \$13.8 million and issued 278,298 shares of our common

stock with an aggregate fair value of \$8.0 million upon the ABON facility being fully functional for the sale of products in Europe. Additionally, on September 27, 2006, we paid cash of approximately \$10.0 million upon the ABON facility achieving certain Chinese regulatory approvals. The August and September 2006 transactions resulted in an increase of \$62.6 million in the preliminary aggregate purchase price.

*Financing Activities*

On February 8 and 9, 2006, we sold an aggregate 3,400,000 shares of our common stock at \$24.41 per share to funds affiliated with 14 accredited institutional investors in a private placement. Proceeds from the private placement were approximately \$79.3 million, net of issuance costs of \$3.7 million. Of this amount, we repaid principal and interest outstanding under our senior credit facility of \$74.1 million, with the remainder of the net proceeds retained for general corporate purposes.

On August 23, 2006, we sold an aggregate 5,000,000 shares of our common stock at \$30.25 per share to funds affiliated with 17 accredited institutional investors in a private placement. Proceeds from the private placement were approximately \$145.5 million, net of issuance costs of \$5.7 million. Of this amount, we used \$41.3 million for payments related to our ABON acquisition, \$5.3 million to purchase the remaining 32.55% of CLONDIAG, repaid principal outstanding under our senior credit facility of \$54.0 million and repaid principal and interest outstanding, along with a prepayment penalty, under our 10% subordinated promissory notes of \$20.8 million, with the remainder of the net proceeds retained for general corporate purposes.

As of September 30, 2006, we had an aggregate of \$1.1 million in outstanding capital lease obligations which are payable through 2009.

*Income Taxes*

As of December 31, 2005, we had approximately \$170.2 million and \$26.0 million of domestic and foreign net operating loss, or NOL, carryforwards, respectively, which either expire on various dates through 2025 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, 2005 included approximately \$71.2 million of pre-acquisition losses from our subsidiaries, Inverness Medical Nutritionals Group, Ischemia, Ostex International, Inc. and Advantage Diagnostics Corporation. The future benefit of these losses will be applied first to reduce to zero any goodwill and other non-current intangible assets related to the acquisitions, prior to reducing our income tax expense. Also included in our domestic NOL carryforwards at December 31, 2005 was approximately \$2.6 million resulting from the exercise of employee stock options, the tax benefit of which, when recognized, will be accounted for as a credit to additional paid-in capital rather than a reduction of income tax. Furthermore, all domestic losses are subject to the Internal Revenue Service Code Section 382 limitation and may be limited in the event of certain cumulative changes in ownership interests of significant shareholders over a three-year period in excess of 50%. Section 382 imposes an annual limitation on the use of these losses to an amount equal to the value of the company at the time of the ownership change multiplied by the long term tax exempt rate. We have recorded a valuation allowance against a portion of the deferred tax assets related to our net operating losses and certain of our other deferred tax assets to reflect uncertainties that might affect the realization of such deferred tax assets, as these assets can only be realized via profitable operations.

**Off-Balance Sheet Arrangements**

We had no material off-balance sheet arrangements as of September 30, 2006.

### **Contractual Obligations**

The following table summarizes our principal contractual obligations as of September 30, 2006 that have changed significantly since December 31, 2005 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 for the year ended December 31, 2005, but omitted in the table below, represent those that have not changed significantly since that date.

<b>Contractual Obligations</b>	<b>Payments Due by Period</b>				
	<b>Total (in thousands)</b>	<b>2006</b>	<b>2007 - 2008</b>	<b>2009 - 2010</b>	<b>Thereafter</b>
Long-term debt obligations(1)	\$ 201,966	\$ 1,320	\$ 50,643	\$ 3	\$ 150,000
Remaining obligations Innovacon/ABON(2)	19,880	9,880	10,000		
Purchase obligations other(3)	39,594	37,186	2,408		
Interest on debt(4)	72,751	4,923	26,256	26,256	15,316
<b>Total</b>	<b>\$ 334,191</b>	<b>\$ 53,309</b>	<b>\$ 89,307</b>	<b>\$ 26,259</b>	<b>\$ 165,316</b>

(1) Long-term debt obligations decreased by \$59.6 million since December 31, 2005, primarily due to our repayment of borrowings under our primary senior credit facility and repayment of our \$20.0 million, 10% subordinated promissory notes during the nine months ended September 30, 2006.

(2) In connection with our acquisition of Innovacon/ABON, we are required to make additional payments of \$19.9 million, of which \$9.9 million will be due upon successful completion of certain milestones and \$10.0 million will be payable to the sellers on the deferred payment date.

(3) Other purchase obligations relate to inventory purchases and other operating expense commitments. Other purchase obligations increased by \$3.8 million, as compared to the commitments at December 31, 2005, primarily due to our efforts to reduce our raw material costs in our nutritional business by executing certain bulk purchase commitments.

(4) Interest on debt includes amounts based on our \$150.0 million senior subordinated notes. Amounts exclude interest on all other debt due to the variable interest rates (see Note 13 of our accompanying consolidated financial statements). Interest on debt decreased by \$13.0 million since December 31, 2005.

As of September 30, 2006, we had outstanding material contingent contractual obligations related to our acquisitions of Binax and CLONDIAG. With respect to Binax, the terms of the acquisition agreement provide for \$11.0 million of contingent cash consideration payable to the Binax shareholders upon the successful completion of certain new product developments during the five years following the acquisition. With respect to the acquisition of CLONDIAG, in the event that the value of the 218,502 shares of common stock issued in connection with the acquisition is less than 4.87 million on December 29, 2006, we will be required to pay the sellers additional cash in the amount of the shortfall. In addition, the terms of the acquisition agreement provide for \$8.9 million of contingent consideration, consisting of 224,316 shares of our common stock and approximately \$3.0 million of cash or stock in the event that four specified products are developed on CLONDIAG's platform technology during the three years following the acquisition date.

### **Critical Accounting Policies**

The consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q are prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The accounting policies discussed below are considered by our management and our audit committee to be critical to an understanding of our financial statements because their application depends on management's judgment, with financial reporting results relying on estimates and assumptions about



the effect of matters that are inherently uncertain. Specific risks for these critical accounting policies are described in the following paragraphs. For all of these policies, management cautions that future events rarely develop exactly as forecast and the best estimates routinely require adjustment. In addition, the notes to our audited consolidated financial statements for the year ended December 31, 2005 included in our Annual Report on Form 10-K include a comprehensive summary of the significant accounting policies and methods used in the preparation of our consolidated financial statements.

*Revenue Recognition*

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

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

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

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

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

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

Our total provision for sales returns and other allowances related to sales incentive arrangements amounted to \$14.2 million and \$38.8 million, or 9% and 9%, respectively, of product sales for the three and nine months ended September 30, 2006, compared to \$11.6 million and \$38.3 million, or 10% and

12%, respectively, of product sales for the three and nine months ended September 30, 2005, 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 \$109.2 million and \$70.5 million, net of allowances for doubtful accounts of \$8.6 million and \$9.7 million, respectively, as of September 30, 2006 and December 31, 2005, 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 periods, our inventory is determined to be overvalued, we would be required to recognize the excess value as a charge to our cost of sales at the time of such determination. Likewise, if, in future periods, our inventory is determined to be undervalued, we would have over-reported our cost of sales, or understated our earnings, at the time we recorded the excess and obsolete provision. Our inventory balance was \$87.0 million and \$71.2 million, net of a provision for excess and obsolete inventory of \$6.8 million and \$7.7 million, as of September 30, 2006 and December 31, 2005, 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, 2006, the balances of property, plant and equipment, goodwill and other intangible assets, net of accumulated depreciation and amortization, were \$80.6 million, \$440.0 million and \$235.0 million, respectively.

Goodwill and other intangible assets are initially created as a result of business combinations or acquisitions of intellectual property. The values we record for goodwill and other intangible assets represent fair values calculated by accepted valuation methods. Such valuations require us to provide significant estimates and assumptions which are derived from information obtained from the management of the acquired businesses and our business plans for the acquired businesses or intellectual property. Critical estimates and assumptions used in the initial valuation of goodwill and other intangible assets include, but are not limited to: (i) future expected cash flows from product sales, customer contracts and acquired developed technologies and patents, (ii) expected costs to complete any in-process research and development projects and commercialize viable products and estimated cash flows from sales of such products, (iii) the acquired companies' brand awareness and market position, (iv) assumptions about the period of time over which we will continue to use the acquired brand, and (v) 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, SFAS No. 142, *Goodwill and Other Intangible Assets*, requires that impairment reviews be performed on the carrying values of all goodwill on at least an annual basis. For all long-lived tangible and intangible assets and goodwill, if an impairment loss is identified based on the fair value of the asset, as compared to the carrying value of the asset, such loss would be charged to expense in the period we identify the impairment. Furthermore, if our review of the carrying values of the long-lived tangible and intangible assets with finite lives indicates impairment of such assets, we may determine that shorter estimated useful lives are more appropriate. In that event, we will be required to record additional depreciation and amortization in future periods, which will reduce our earnings.

#### *Valuation of Goodwill*

We have goodwill balances related to our consumer diagnostics and professional diagnostics (which includes cardiology) reporting units, which amounted to \$86.0 million and \$354.0 million, respectively, as of September 30, 2006. As of September 30, 2005, we performed our annual impairment review on the carrying values of such goodwill using the discounted cash flows approach. Based upon this review, we do not believe that the goodwill related to our consumer diagnostics and professional diagnostics reporting units were impaired. Because future cash flows and operating results used in the impairment review are based on management's projections and assumptions, future events can cause such projections to differ from those used at September 30, 2005, 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, 2005, that would require us to reassess whether the carrying values of our goodwill have been impaired.

#### *Valuation of Other Long-Lived Tangible and Intangible Assets*

Factors we generally consider important which could trigger an impairment review on the carrying value of other long-lived tangible and intangible assets include the following: (1) significant underperformance relative to expected historical or projected future operating results; (2) significant changes in the manner of our use of acquired assets or the strategy for our overall business; (3) underutilization of our tangible assets; (4) discontinuance of product lines by ourselves or our customers; (5) significant negative industry or economic trends; (6) significant decline in our stock price for a sustained period; (7) significant decline in our market capitalization relative to net book value; and (8) goodwill impairment identified during an impairment review under SFAS No. 142. Although we believe that the carrying value of our long-lived tangible and intangible assets was realizable as of September 30, 2006, 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.

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

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

### *Accounting for Income Taxes*

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

Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have recorded a valuation allowance of \$96.7 million as of December 31, 2005 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.

In accordance with SFAS No. 109, *Accounting for Income Taxes*, and SFAS No. 5, *Accounting for Contingencies*, we established reserves for tax contingencies that reflect our best estimate of the transactions and deductions that we may be unable to sustain or that we could be willing to concede as part of a broader tax settlement. We are currently undergoing routine tax examinations by various state and foreign jurisdictions. Tax authorities periodically challenge certain transactions and deductions we reported on our income tax returns. We do not expect the outcome of these examinations, either individually or in the aggregate, to have a material adverse effect on our financial position, results of operations, or cash flows.

It has been our company's 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*

Due to the nature of our business, we may from time to time be subject to commercial disputes, consumer product claims or various other lawsuits arising in the ordinary course of our business, and we expect this will continue to be the case in the future. These lawsuits generally seek damages, sometimes in substantial amounts, for commercial or personal injuries allegedly suffered and can include claims for

punitive or other special damages. In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties, which can be expensive and can result in counterclaims against us. We are currently not a party to any material legal proceedings.

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.

### **Recently Issued Accounting Standards**

#### *Recently Issued Standards*

In February 2006, the Financial Accounting Standards Board ( FASB ) issued Statement SFAS No. 155, *Accounting for Certain Hybrid Financial Instruments*, which amends SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* and SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*. SFAS No. 155 simplifies the accounting for certain derivatives embedded in other financial instruments by allowing them to be accounted for as a whole if the holder elects to account for the whole instrument on a fair value basis. SFAS No. 155 also clarifies and amends certain other provisions of SFAS No. 133 and SFAS No. 140. SFAS No. 155 is effective for all financial instruments acquired, issued or subject to a remeasurement event occurring in fiscal years beginning after September 15, 2006. Earlier adoption is permitted, provided we have not yet issued financial statements, including for interim periods, for that fiscal year. We do not expect the adoption of SFAS No. 155 to have a material impact on our financial position, results of operations or cash flows.

In June 2006, the FASB ratified the consensus on Emerging Issues Task Force ( EITF ) Issue No. 06-03, *How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement*. The scope of EITF Issue No. 06-03 includes any tax assessed by a governmental authority that is directly imposed on a revenue-producing transaction between a seller and a customer and may include, but is not limited to, sales, use, value added, Universal Service Fund contributions and some excise taxes. The Task Force affirmed its conclusion that entities should present these taxes in the income statement on either a gross or a net basis, based on their accounting policy, which should be disclosed pursuant to APB Opinion No. 22, *Disclosure of Accounting Policies*. If such taxes are significant, and are presented on a gross basis, the amounts of those taxes should be disclosed. The consensus on EITF Issue No. 06-03 will be effective for interim and annual reporting periods beginning after December 15, 2006. We are currently evaluating impact of EITF Issue No. 06-03. Should we need to change the manner in which we record gross receipts, it is not expected that the change would have a material impact on total operating revenue and expenses and operating income and net income would not be affected.

In June 2006, the FASB issued FASB Interpretation No. ( FIN ) 48, *Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109*. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, *Accounting for Income Taxes*. FIN 48 prescribes a recognition threshold and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 is effective for fiscal years beginning after December 15, 2006. We are currently evaluating the impact of the adoption of FIN 48 on our financial statements, but it is not expected to be material.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*. SFAS No. 157 establishes a framework for measuring fair value in generally accepted accounting principles, and expands

disclosures about fair value measurements. The standard applies whenever other standards require (or permit) assets or liabilities to be measured at fair value. The standard does not expand the use of fair value in any new circumstances. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. Earlier application is encouraged. We have not yet determined the effect the adoption of SFAS No. 157 will have on our financial position, results of operations or cash flows.

In September 2006, the FASB issued SFAS No. 158, *Employers Accounting for Defined Benefit Pension and Other Postretirement Plan An Amendment of FASB Statements No. 87, 88, 106 and 132(R)*. SFAS No. 158 requires an employer to recognize the overfunded or underfunded status of a defined benefit postretirement plan (other than a multiemployer plan) as an asset or liability in its statement of financial position and to recognize changes in that funded status in the year in which the changes occur through other comprehensive income. SFAS No. 158 also requires the measurement of defined benefit plan assets and obligations as of the fiscal year end, in addition to footnote disclosures. As our common stock is a publicly traded equity security, we are required to recognize the funded status of defined benefit pension plans (we do not have other postretirement benefit plans) and to provide the required footnote disclosures, as of the end of this fiscal year ending December 31, 2006. We will adopt SFAS No. 158 on January 1, 2007.

In September 2006, the SEC issued Staff Accounting Bulletin ( SAB ) No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements*, to provide guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. Under SAB No. 108, companies should evaluate a misstatement based on its impact on the current year income statement, as well as the cumulative effect of correcting such misstatements that existed in prior years existing in the current year's ending balance sheet. SAB No. 108 is effective for fiscal years ending after November 15, 2006. We have not determined the effect the adoption of SAB No. 108 will have on our financial position, results of operations or cash flows.

#### **Recently Adopted Accounting Standards**

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs an Amendment of ARB No. 43, Chapter 4*. SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted materials (spoilage). In addition, this statement requires that allocation of fixed production overheads to the costs of conversion be based on normal capacity of production facilities. As required by SFAS No. 151, we adopted this new accounting standard on January 1, 2006. The adoption of SFAS No. 151 did not have a material impact on our financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123-R, *Share-Based Payment*, which addresses the accounting for transactions in which a company receives employee services in exchange for (a) equity instruments of the company or (b) liabilities that are based on the fair value of the company's equity instruments or that may be settled by the issuance of such equity instruments. Under the original guidance of SFAS No. 123-R, we were to adopt the statement's provisions for the interim period beginning after June 15, 2005. However, in April 2005, as a result of an action by the Securities and Exchange Commission, companies were allowed to adopt the provisions of SFAS No. 123-R at the beginning of their fiscal year that begins after June 15, 2005. Consequently, we adopted SFAS No. 123-R on January 1, 2006. See Note 4 in our accompanying consolidated financial statements for further discussion.

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections*, which replaces APB Opinion No. 20, *Accounting Changes*, and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*. The statement requires a voluntary change in accounting principle be applied retrospectively to all prior period financial statements so that those financial statements are presented as if

the current accounting principle had always been applied. APB Opinion No. 20 previously required most voluntary changes in accounting principle to be recognized by including in net income of the period of change the cumulative effect of changing to the new accounting principle. In addition, SFAS No. 154 carries forward, without change, the guidance contained in APB Opinion No. 20 for reporting a correction of an error in previously issued financial statements and a change in accounting estimate. SFAS No. 154 was effective for accounting changes and corrections of errors made after January 1, 2006. The adoption of SFAS No. 154 had no impact on our financial statements.

#### 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, estimate, continue or similar words. You should read statements that contain these words carefully because they discuss our future expectations, contain projections of our future results of operations or of our financial condition or state other forward-looking information. There may be events in the future that we are not able to predict accurately or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. We caution investors that all forward-looking statements involve risks and uncertainties, and actual results may differ materially from those we discuss in this report. These differences may be the result of various factors, including those factors described in Part I, Item 1A, Risk Factors, of our Annual Report on Form 10-K for the fiscal year ending December 31, 2005 and other risk factors identified herein or from time to time in our periodic filings with the SEC. Some important factors that could cause our actual results to differ materially from those projected in any such forward-looking statements are as follows:

- economic factors, including inflation and fluctuations in interest rates and foreign currency exchange rates, and the potential effect of such fluctuations on revenues, expenses and resulting margins;
- competitive factors, including technological advances achieved and patents attained by competitors and generic competition;
- domestic and foreign healthcare changes resulting in pricing pressures, including the continued consolidation among healthcare providers, trends toward managed care and healthcare cost containment and government laws and regulations relating to sales and promotion, reimbursement and pricing generally;
- government laws and regulations affecting domestic and foreign operations, including those relating to trade, monetary and fiscal policies, taxes, price controls, regulatory approval of new products and licensing;
- manufacturing interruptions, delays or capacity constraints or lack of availability of alternative sources for components for our products, including our ability to successfully maintain relationships with suppliers, or to put in place alternative suppliers on terms that are acceptable to us;
- difficulties inherent in product development or arising out of ABI's subjection to the FDA's Application Integrity Policy, including the potential inability to successfully continue technological innovation, complete clinical trials, obtain regulatory approvals in the United States and abroad, gain and maintain market approval of products and the possibility of encountering infringement claims by competitors with respect to patent or other intellectual property rights which can preclude or delay commercialization of a product;

- significant litigation adverse to us including product liability claims, patent infringement claims and antitrust claims;
- our ability to comply with regulatory requirements, including the outcome of the SEC's ongoing investigation into the revenue recognition issues at our Wampole subsidiary disclosed in June 2005 and the ongoing inquiry by the Federal Trade Commission into our acquisition of certain assets from Acon Laboratories;
- product efficacy or safety concerns resulting in product recalls or declining sales;
- the impact of business combinations and organizational restructurings consistent with evolving business strategies;
- our ability to reach a definitive agreement with The Procter & Gamble Company regarding the proposed joint venture transaction that we have previously announced and our ability to complete the proposed joint venture;
- 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.

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, 2006, our short-term investments approximated market value.

At September 30, 2006, we had a term loan and revolving lines of credit available to us of up to \$155.0 million in the aggregate under our primary senior credit facility, against which \$45.0 million was



outstanding under the term loan. At September 30, 2006, there were no amounts outstanding under the revolving lines of credit. We may repay any borrowings under the revolving lines of credit at any time but in no event later than March 31, 2008. Borrowings under the revolving lines of credit bear interest at either (i) the London Interbank Offered Rate, or LIBOR, as defined in the credit agreement, plus applicable margins or, at our option, (ii) a floating index rate ( Index Rate ), as defined in the agreement, plus applicable margins. Applicable margins, if we choose to use the LIBOR or the Index Rate can range from 2.75% to 3.75% or 1.50% to 2.50%, respectively, depending on the quarterly adjustments that are based on our consolidated financial performance.

As of September 30, 2006, the LIBOR and Index Rate applicable under our primary senior credit facility for the U.S. term loan were 9.33% and 10.5%, respectively. Assuming no changes in our leverage ratio, which would affect the margin of the interest rate under the senior credit agreement, the effect of interest rate fluctuations on outstanding borrowings under the revolving lines of credit as of September 30, 2006 over the next twelve months is quantified and summarized as follows (in thousands):

	<b>Interest Expense Increase</b>
Interest rates increase by 1 percentage point	\$ 450
Interest rates increase by 2 percentage points	\$ 900

#### **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, 2006, the net impact of foreign currency changes on transactions was a loss of \$0.1 million and a gain of \$3.2 million, respectively. The foreign currency gain for the nine months ended September 30, 2006 includes the impact of a \$4.3 million gain resulting from the closure of our CDIL operation in Galway, Ireland. 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. Dollars are also affected by foreign currency exchange rate movements. Our gross margin on total net product sales was 41.5% for the three months ended September 30, 2006. 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, 2006, our gross margin on total net product sales would have been 41.6%, 41.9% and 42.3%, respectively. Our gross margin on total net product sales was 38.1% for the nine months ended September 30, 2006. 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, 2006, our gross margin on total net product sales would have been 38.5%, 38.9% and 39.4%, respectively.

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

<b>If, during the three months ended September 30, 2006, the U.S. dollar was stronger by:</b>	<b>Approximate decrease in net revenue</b>	<b>Approximate increase in net loss</b>
1%	\$ 412	\$ 3
5%	\$ 2,058	\$ 13
10%	\$ 4,116	\$ 26

<b>If, during the nine months ended September 30, 2006, the U.S. dollar was stronger by:</b>	<b>Approximate decrease in net revenue</b>	<b>Approximate increase in net loss</b>
1%	\$ 1,241	\$ 37
5%	\$ 6,203	\$ 185
10%	\$ 12,406	\$ 370

#### ITEM 4. CONTROLS AND PROCEDURES

##### *Evaluation of Disclosure Controls and Procedures*

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

##### *Changes in Internal Control over Financial Reporting*

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

**PART II OTHER INFORMATION**

**ITEM 1A. RISK FACTORS**

There have been no material changes from the Risk Factors previously disclosed in Part I, Item 1A, "Risk Factors," of our Annual Report on Form 10-K for the fiscal year ending December 31, 2005, as supplemented by any material changes or additions to such risk factors disclosed in Part II, Item 1A, "Risk Factors," of any Quarterly Report on Form 10-Q filed subsequent to the Annual Report on Form 10-K.

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

On August 29, 2006 and September 1, 2006, pursuant to the terms of our acquisition agreement with ACON Laboratories, Inc. and certain affiliates, we issued a total of 742,128 shares of common stock to Manfield Top Worldwide Ltd. and Overseas Square Ltd., two affiliates of ACON Laboratories, in connection with milestone payments due under the agreement. The issuances were conducted pursuant to an exemption afforded by Section 4(2) of the Securities Act of 1933, as amended.

**ITEM 6. EXHIBITS**

**Exhibits:**

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

### Exhibit No.

	<b>Description</b>
*10.1	Sixth Amendment And Consent To Third Amended And Restated Credit Agreement, dated as of May 3, 2006, to the Third Amended and Restated Credit Agreement, dated as of June 30, 2005 (as amended, supplemented or otherwise modified from time to time), by and among General Electric Capital Corporation, as Agent, Inverness Medical Innovations, Inc., Wampole Laboratories, LLC and Inverness Medical (UK) Holdings Limited, as Borrowers, the other Credit Parties signatory thereto, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as documentation agent, co-syndication agent and lender, UBS Securities LLC, as co-syndication agent, and the Lenders signatory thereto from time to time.
*10.2	Seventh Amendment And Consent To Third Amended And Restated Credit Agreement, dated as of October 6, 2006, to the Third Amended and Restated Credit Agreement, dated as of June 30, 2005 (as amended, supplemented or otherwise modified from time to time), by and among General Electric Capital Corporation, as Agent, Inverness Medical Innovations, Inc., Wampole Laboratories, LLC and Inverness Medical (UK) Holdings Limited, as Borrowers, the other Credit Parties signatory thereto, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as documentation agent, co-syndication agent and lender, UBS Securities LLC, as co-syndication agent, and the Lenders signatory thereto from time to time.
*10.3	Eighth Amendment And Consent To Third Amended And Restated Credit Agreement, dated as of October 30, 2006, to the Third Amended and Restated Credit Agreement, dated as of June 30, 2005 (as amended, supplemented or otherwise modified from time to time), by and among General Electric Capital Corporation, as Agent, Inverness Medical Innovations, Inc., Wampole Laboratories, LLC and Inverness Medical (UK) Holdings Limited, as Borrowers, the other Credit Parties signatory thereto, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as documentation agent, co-syndication agent and lender, UBS Securities LLC, as co-syndication agent, and the Lenders signatory thereto from time to time.

56

---

- \*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
-

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

\* filed herewith

57

---

**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.

Date: November 8, 2006

INVERNESS MEDICAL INNOVATIONS, INC.

/s/ CHRISTOPHER J. LINDOP

Christopher J. Lindop

*Chief Financial Officer and an authorized officer*