INVERNESS MEDICAL INNOVATIONS INC
Form 10-Q/A
August 26, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q/A

Amendment No. 1

(Mark One)

ý Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

for the quarterly period ended March 31, 2005

OR

o Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

for the transition period from to

COMMISSION FILE NUMBER 001-16789

INVERNESS MEDICAL INNOVATIONS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

DELAWARE	**04-3565120**
(State or other jurisdiction of incorporation or organization)	(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 ý No o

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Exchange Act).

Yes ý No o

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

Yes o No ý

The number of shares outstanding of the registrant s common stock as of May 6, 2005 was 23,210,888.

INVERNESS MEDICAL INNOVATIONS, INC.

FORM 10-Q

For the Quarterly Period Ended March 31, 2005

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 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 this quarterly report on Form 10-Q and other risk factors identified from time to time in our periodic filings with the Securities and Exchange Commission. Readers should carefully review the factors discussed in the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations Certain Factors Affecting Future Results and Special Statement Regarding Forward-Looking Statements beginning on pages 34 and 46, respectively, 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.

References in this quarterly report on Form 10-Q to we, us, and our refer to Inverness Medical Innovations, Inc. and its subsidiaries.

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EXPLANATORY NOTE

On June 28, 2005, we announced that certain of our previously issued financial statements must be restated because they contain errors under accounting principles generally accepted in the United States of America (GAAP) relating to the recognition of revenue at one of our diagnostic divisions. We had determined that certain customers of this division were provided return or exchange rights in connection with the sale of certain products for which reliable estimates of return or exchange had not been made, as a result of which the revenues associated with these sales should not have been recognized upon shipment to the customers under GAAP. Since that time the Audit Committee of our Board of Directors conducted an investigation into these matters using independent special counsel. The results of this investigation contributed to our determination that the necessary restatement required $4.2 million in net revenue reversal with a $3.1 million gross profit and corresponding net loss impact spread over the quarters of 2003 and 2004 and the first quarter of 2005. We are filing this Amendment No. 1 (the Amended Report) to our Quarterly Report on Form 10Q for the quarter ended March 31, 2005 (the Original Report) in order to restate our financial statements included therein to reflect these findings. We also restated our audited financial statements for the periods ended December 31, 2004 and December 31, 2003 included in Amendment No. 1 to our Annual Report on Form 10-K for the period ended December 31, 2004, as well as unaudited financial statements for the periods ended September 30, 2004 and September 30, 2003 included in Amendment No. 2 to our Quarterly Report on Form 10-Q for the period ended September 30, 2004. In addition, our Quarterly Report on Form 10-Q for the period ended June 30, 2005, contained unaudited financial statements for the periods ended June 30, 2005 and June 30, 2004 that reflect these findings.

For the reasons discussed above, we are filing this Amended Report in order to amend Part I. Item 1 Financial Statements, Part I. Item 2 Management s Discussion and Analysis of Financial Condition and Results of Operations, Part I. Item 3 Quantitative and Qualitative Disclosures About Market Risk, Part I. Item 4 Controls and Procedures and Part II. Item 6 Exhibits of the Original Report to the extent necessary to reflect the adjustments discussed above and to reflect the results of our evaluations of disclosure controls and procedures and internal control over financial reporting, taking into consideration these restatements. The remaining Items of our Original Report are not amended hereby and are repeated herein only for the reader s convenience.

In order to preserve the nature and character of the disclosures set forth in the Original Report, except as expressly noted above, this report speaks as of the date of the filing of the Original Report, May 10, 2005, and we have not updated the disclosures in this report to speak as of a later date. All information contained in this Amended Report is subject to updating and supplementing as provided in our reports filed with the SEC subsequent to the date of the Original Report.

PART I - **FINANCIAL INFORMATION**

ITEM 1. **FINANCIAL STATEMENTS**

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2005	**2004**
		(restated)
Net product sales	$ 89,699	$ 88,608
License revenue	2,221	2,500
Net revenue	91,920	91,108
Cost of sales	59,731	53,911
Gross profit	32,189	37,197
Operating expenses:		
Research and development (Note 9)	7,232	7,423
Sales and marketing	17,030	14,351
General and administrative	14,115	11,320
Total operating expenses	38,377	33,094
Operating (loss) income	(6,188)	4,103
Interest expense, including amortization of discounts and write-off of deferred financing costs	(5,012)	(7,770)
Other income, net	4,911	447
Loss before income taxes	(6,289)	(3,220)
Income tax provision	1,513	163
Net loss	$ (7,802)	$ (3,383)
Net loss available to common stockholders basic and diluted (Note 6)	$ (7,802)	$ (4,132)
Net loss per common share basic and diluted (Note 6)	$ (0.37)	$ (0.22)
Weighted average shares basic and diluted (Note 6)	20,942	19,216

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)

	March 31, 2005	December 31, 2004 (restated)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,667	$ 16,756
Accounts receivable, net of allowances of $9,973 at March 31, 2005 and $9,359 at December 31, 2004	57,814	61,347
Inventories	66,513	61,234
Deferred tax assets	2,961	2,819
Prepaid expenses and other current assets	14,128	9,601
Total current assets	175,083	151,757
Property, plant and equipment, net	69,244	66,780
Goodwill	258,886	221,155
Other intangible assets with indefinite lives	55,356	50,542
Core technology and patents, net	68,540	40,327
Other intangible assets, net	35,445	27,680
Deferred financing costs, net, and other non-current assets	9,335	9,156
Deferred tax assets	794	872
Total assets	$ 672,683	$ 568,269
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 329	$ 88
Current portion of capital lease obligations	492	467
Accounts payable	39,471	32,345
Accrued expenses and other current liabilities	66,336	56,242
Total current liabilities	106,628	89,142
Long-term liabilities:		
Long-term debt, net of current portion	211,315	189,268
Capital lease obligations, net of current portion	1,312	1,401
Deferred tax liabilities	28,726	12,596
Other long-term liabilities	4,721	4,446
Total long-term liabilities	246,074	207,711
Commitments and contingencies		
Series A redeemable convertible preferred stock, $0.001 par value:		
Authorized 2,667 shares		
Issued 2,527 shares		
Outstanding none		
Stockholders equity:		
Preferred stock, $0.001 par value:		
Authorized 2,333 shares, none issued		
Common stock, $0.001 par value:		
Authorized 50,000 shares		
Issued and outstanding 23,191 at March 31, 2005 and 20,711 shares at December 31, 2004	23	21

Additional paid-in capital		418,440		359,582
Notes receivable from stockholders		(14,691)		(14,691)
Accumulated deficit		(98,819)		(91,017)
Accumulated other comprehensive income		15,028		17,521
Total stockholders equity		319,981		271,416
Total liabilities and stockholders equity	$	672,683	$	568,269

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)

	Three Months Ended March 31,	
	2005	**2004 (restated)**
Cash Flows from Operating Activities:		
Net loss	$ (7,802)	$ (3,383)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Interest expense related to amortization and/or write-off of noncash original issue discount and deferred financing costs	443	3,311
Noncash charge related to interest rate swap agreement		64
Depreciation and amortization	6,202	5,575
Deferred income taxes	638	(701)
Other noncash items	(68)	(19)
Minority interest	207	
Changes in assets and liabilities, net of acquisitions:		
Accounts receivable, net	8,688	23
Inventories	(2,997)	(3,322)
Prepaid expenses and other current assets	(4,476)	596
Accounts payable	5,348	(5,820)
Accrued expenses and other current liabilities	9,048	1,963
Other non-current liabilities	76	
Net cash provided by (used in) operating activities	15,307	(1,713)
Cash Flows from Investing Activities:		
Purchases of property, plant and equipment	(3,979)	(4,401)
Proceeds from sale of property, plant and equipment	43	28
Payments for acquisitions and of transactional costs for previous acquisitions	(15,776)	(2,364)
Increase in other assets	(394)	(815)
Net cash used in investing activities	(20,106)	(7,552)
Cash Flows from Financing Activities:		
Cash paid for financing costs	(355)	(4,666)
Proceeds from issuance of common stock, net of issuance costs	899	521
Proceeds from issuance of senior subordinated notes		150,000
Net proceeds (repayment) under revolving line of credit	22,170	(40,460)
Repayments of notes payable	(9)	(94,241)
Principal payments of capital lease obligations	(115)	(107)
Net cash provided by financing activities	22,590	11,047
Foreign exchange effect on cash and cash equivalents	(880)	(262)
Net increase in cash and cash equivalents	16,911	1,520
Cash and cash equivalents, beginning of period	16,756	24,622
Cash and cash equivalents, end of period	$ 33,667	$ 26,142
Supplemental Disclosure of Noncash Activities:		
Dividends, redemption interest and amortization of beneficial conversion feature related to preferred stock	$	$ 749
Fair value of stock issued for acquisitions	$ 57,962	$

Conversion of preferred stock to common stock	$	$ 6,934

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 the instructions for Form 10-Q and therefore do not include all information and footnotes necessary for a complete presentation of operations, financial position, and cash flows in conformity with accounting principles generally accepted in the United States of America (GAAP). Our audited consolidated financial statements for the year ended December 31, 2004 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 16, 2005. 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, 2004.

We are restating the financial results of our previously issued consolidated financial statements as of March 31, 2005 and December 31, 2004 and for the three months ended March 31, 2005 and 2004, to correct errors under GAAP relating to the recognition of revenue. Such adjustments are reflected in the accompanying consolidated interim financial information, as discussed in Note 2 below.

(2) Restatement

We are restating the financial results of our previously issued consolidated financial statements as of March 31, 2005 and December 31,2004 and for the three months ended March 31, 2005 and 2004, to correct errors under GAAP relating to the recognition of revenue. We determined that certain customers of one of our diagnostics divisions were provided return or exchange rights in connection with the sale of certain products for which reliable estimates of returns or exchange had not been made, as a result of which the revenue associated with those sales should not have been recognized upon shipment to the customers under GAAP. As a result, we recorded an aggregate increase of $0.7 million in net revenue with an impact of increasing gross profit and decreasing our net loss by an aggregate $0.6 million in the combined first quarters of 2005 and 2004.

The following lists the accounts in the consolidated statements of operations and balance sheets that were affected by the aforementioned restatements, with comparisons of the restated amounts to the originally reported amounts and the effect of such restatements on net revenues, net loss and loss per share. All applicable amounts relating to the aforementioned restatements have been reflected in these consolidated financial statements and notes hereto.

(in thousands, except per share amounts)	Three Months Ended March 31, 2005 As restated	Three Months Ended March 31, 2005 As reported	Three Months Ended March 31 ,2004 As restated	Three Months Ended March 31 ,2004 As reported
Net product sales	$ 89,699	$ 89,391	$ 88,608	$ 88,201
Cost of sales	59,731	59,716	53,911	53,792
Net loss	(7,802)	(8,095)	(3,383)	(3,671)
Net loss available to common stockholders basic and diluted	(7,802)	(8,095)	(4,132)	(4,420)
Pro forma net loss per common share basic and diluted	$ (0.37)	$ (0.39)	$ (0.22)	$ (0.23)

(in thousands, except per share amounts)	March 31, 2005 As restated	March 31, 2005 As reported	December 31, 2004 As restated	December 31, 2004 As reported
Inventories	$ 66,513	$ 65,437	$ 61,234	$ 60,143
Accrued expenses and other current liabilities	66,336	62,288	56,242	51,886
Accumulated Deficit	98,819	95,847	91,017	87,752

All applicable amounts relating to the aforementioned restatements have been reflected in these consolidated financial statements and notes hereto.

(3) Cash and Cash Equivalents

We consider all highly liquid cash investments with original maturities of three months or less at the date of acquisition to be cash equivalents. At March 31, 2005, our cash equivalents consisted of money market funds.

(4) Inventories

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

(in thousands)	March 31, 2005	December 31, 2004 (restated)
Raw materials	$ 25,866	$ 23,434
Work-in-process	16,419	14,956
Finished goods	24,228	22,844
	$ 66,513	$ 61,234

(5) Employee Stock-Based Compensation Arrangements

For all periods presented in the accompanying unaudited consolidated financial statements, we accounted for our employee stock-based compensation arrangements using the intrinsic value method under the provisions of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and in accordance with Financial Accounting Standards Board (FASB) Interpretation (FIN) No. 44, *Accounting for Certain Transactions Involving Stock Compensation*. We have elected to use the disclosure-only provisions of Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation*, and SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure.*

Had compensation expense for stock option grants to employees been determined based on the fair value method at the grant dates for awards under the stock option plans consistent with the method prescribed by SFAS No. 123, our net loss would have been increased to the pro forma amounts indicated as follows:

(in thousands, except per share amounts)	Three Months Ended March 31, 2005	2004 (restated)
Net loss as reported	$ (7,802)	$ (3,383)
Pro forma stock-based employee compensation	(1,586)	(1,603)
Net loss pro forma	$ (9,388)	$ (4,986)
Loss per share basic and diluted:		
Net loss per share as reported	$ (0.37)	$ (0.22)
Pro forma stock-based employee compensation	(0.07)	(0.08)
Net loss per share pro forma	$ (0.44)	$ (0.30)

We have computed the pro forma disclosures for stock options granted to employees after January 1, 1995 using the Black-Scholes option pricing model prescribed by SFAS No. 123. The assumptions used were as follows:

	Three Months Ended March 31, 2005	2004
Risk-free interest rate	3.58-3.73%	2.8-3.39%
Expected dividend yield		
Expected lives	5 years	5 years
Expected volatility	46%	49%

The weighted average fair value under the Black-Scholes option pricing model of options granted to employees during the three months ended March 31, 2005 and 2004 were $10.60 and $9.48, respectively.

(6) Loss Per Share

The following table sets forth the computation of basic and diluted loss per share:

(in thousands, except per share amounts)	Three Months Ended March 31, 2005	2004 (restated)
Numerator:		
Net loss	$ (7,802)	$ (3,383)
Dividends, redemption interest and amortization of beneficial conversion feature related to Series A Preferred Stock		(749)
Net loss available to common stockholders basic and diluted	$ (7,802)	$ (4,132)
Denominator:		
Denominator for basic and diluted loss per share weighted average shares	20,942	19,216

Net loss per share	basic and diluted	$	(0.37)	$	(0.22)

We had the following potential dilutive securities outstanding on March 31, 2005: (a) options and warrants to purchase an aggregate of 4.3 million shares of common stock at a weighted average exercise price of $16.58 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 loss per share because the effect of including such potential dilutive securities would be antidilutive.

We had the following potential dilutive securities outstanding on March 31, 2004: (a) options and warrants to purchase an aggregate of 4.1 million shares of common stock at a weighted average exercise price of $15.83 per share, (b) 498,000 shares of unvested restricted common stock issued to certain executive officers, and (c) convertible promissory notes that are convertible into an aggregate of 344,000 shares of common stock. These potential dilutive securities were not included in the computation of diluted loss per share because the effect of including such potential dilutive securities would be antidilutive.

(7) Comprehensive Income or Loss

Comprehensive income or loss represents net income or loss plus other comprehensive income or loss items. Our other comprehensive income or loss includes primarily foreign currency translation adjustments.. For the three months ended March 31, 2005 and 2004, we generated a comprehensive loss of $10.3 million and $3.0 million, respectively.

(8) Business Combinations

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

(a) Acquisition of Binax

On March 31, 2005, we acquired Binax, Inc (Binax), a privately held developer, manufacturer and distributor of rapid diagnostic products for infectious disease testing, primarily related to the respiratory system. The preliminary aggregate purchase price was $44.7 million which consisted of $9.0 million in cash, 1.4 million shares of our common stock with an aggregate fair value of $35.2 million and $0.5 million in estimated direct acquisition costs. The terms of the acquisition agreement also 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 next five years. This contingent consideration will be accounted for as an increase in the preliminary aggregate purchase price and goodwill if and when the contingency is met.

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

		(in thousands)
Cash and cash equivalents	$	1,556
Accounts receivable		5,264
Inventories		2,548
Property, plant and equipment		2,421

Goodwill		25,178
Core technology and intangible assets		15,000
Other assets		984
Accounts payable and accrued expenses		(2,300)
Deferred tax liability		(6,000)
	$	44,651

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 core technology and intangible assets as listed above.

The acquisition of Binax is accounted for as a purchase under SFAS No. 141, *Business Combinations*. Accordingly, the operating results of Binax will be included in the accompanying consolidated financial statements since the acquisition date as part of our professional diagnostic products reporting units and business segment. Goodwill generated from this acquisition is not deductible for tax purposes.

(b) Acquisition of Ischemia

On March 16, 2005, we acquired Ischemia Technologies, Inc (Ischemia), a privately held, venture-backed company that developed, manufactures and markets the only FDA-cleared *in vitro* diagnostic test targeted on cardiac ischemia. The preliminary aggregate purchase price was $27.2 million, which consisted of 968,000 shares of our common stock with an aggregate fair value of $22.7 million, estimated exit costs of $1.7 million to vacate Ischemia s manufacturing and administrative facilities, which we recorded in accordance with Emerging Issues Task Force (EITF) Issue No. 95-3, *Recognition of Liabilities in Connection with a Purchase Business Combination,* estimated direct acquisition costs of $2.3 million and $0.5 million in assumed debt.

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

		(in thousands)
Cash and cash equivalents	$	115
Accounts receivable		58
Inventories		40
Property, plant and equipment		469
Goodwill		12,400
Core technology and patents		24,000
Other assets		99
Accounts payable and accrued expenses		(377)
Deferred tax liability		(9,600)
	$	27,204

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 values. Management is also in the process of determining the useful lives of the core technology and patents as listed above.

The acquisition of Ischemia is accounted for as a purchase under SFAS No. 141. Accordingly, the operating results of Ischemia have been included in the accompanying consolidated financial statements since the acquisition date as part of our professional diagnostic products reporting units and business segments. Goodwill generated from this acquisition is not deductible for tax purposes.

(c) Acquisition of ACS

On January 24, 2005, we acquired the consumer pregnancy test business of Advanced Clinical Systems Pty Ltd (ACS). In acquiring ACS, we obtained the rights to the Crystal Clear brand. Crystal Clear is the leading consumer pregnancy test in Australia and has a leading position in New Zealand. The purchase price of ACS consisted of $4.6 million in cash and estimated direct acquisition costs of $0.3 million. The majority of the purchase price of ACS is allocated to the intangible asset, trademarks, with an average useful life of 7 years.

(d) Pro Forma Financial Information

The following table presents selected unaudited financial information of our company, including Binax and Ischemia, as if the acquisitions of these entities had occurred on January 1, 2004. Pro forma results exclude adjustments for ACS as the acquisition 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 consumated on January 1, 2004.

(in thousands, except per share amounts)	Three Months Ended March 31, 2005	2004 (restated)
Pro forma net revenue	$ 101,749	$ 97,870
Pro forma net loss	(5,703)	(3,090)
Net loss available to common stockholders basic and diluted (1)	(5,703)	(3,839)
Pro forma net loss per common share basic and diluted (1)	$ (0.25)	$ (0.18)

(1) Loss per share amounts are computed as described in Note 6.

(e) Restructuring Plans of Acquisitions

In connection with our acquisitions of 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. The following table sets forth the restructuring costs and balances recorded in connection with the restructuring activities of these acquired businesses:

(in thousands)	Balance at December 31, 2004	Costs Added to Purchase Price	Amounts Paid	Other (1)	Balance at March 31, 2005
Ischemia	$	$ 1,690	$ (1,039)	$	$ 651
Ostex	910		(72)		838
IMN	263		(115)		148
Unipath business	1,453			(27)	1,426
Total restructuring costs	$ 2,626	$ 1,690	$ (1,226)	$ (27)	$ 3,063

(1) Represents foreign currency translation adjustment.

In connection with our acquisition of Ischemia in March 2005, we established a restructuring plan whereby we will exit the current facilities of Ischemia in Denver, Colorado, and combine its activities with our existing manufacturing and distribution facilities by mid-2005. Total severance costs associated with involuntarily terminated employees are estimated to be $1.6 million, of which $1.0 million has been paid as of

March 31, 2005. We estimated costs to vacate the Ischemia facilities to be approximately $100,000, none of which has been paid as of March 31, 2005. The total number of involuntarily terminated employees was 17, of whom 7 were terminated as of March 31, 2005. 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.

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 terminated involuntarily under the restructuring plan is 38, of which all were terminated as of March 31, 2005. Total severance costs associated with involuntarily terminated employees are $1.6 million, of which all has been paid as of March 31, 2005. Costs to vacate the Ostex facilities are $0.5 million, of which $0.2 million has been paid as of March 31, 2005. Additionally, the remaining costs to exit operations, primarily facilities lease commitments, are $1.9 million, of which $1.4 million has been paid as of March 31, 2005. Total unpaid exit costs amounted to $0.8 million as of March 31, 2005.

Immediately after the close of the acquisition, we reorganized the business operations of IMN 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 include severance costs of 47 involuntarily terminated employees and costs to vacate the warehouse, $1.4 million has been paid and $0.2 million remains unpaid as of March 31, 2005.

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 of 65 involuntarily terminated employees, were $4.1 million. As of March 31, 2005, $1.4 million, adjusted for foreign exchange effect, in exit costs remained unpaid.

(9) 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 approximately £30 million (or $56.5 million at March 31, 2005) 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 (or $70.6 million at March 31, 2005) in the programs over the next three years. Through our subsidiary, Stirling Medical Innovations Limited (Stirling), we intend to establish a new research center in Stirling, Scotland, where we will consolidate many of our existing cardiology programs and ultimately commercialize products arising from the programs. ITI and Stirling will have exclusive rights to the developed technology in their respective fields of use. As of March 31, 2005, we had received approximately $11 million in funding from ITI. As qualified expenditures are made under the co-development arrangement, we recognize the fee earned during the period as a reduction of our related expenses, subject to certain limitations. For the three months ended March 31, 2005, we recognized $2.2 million of reimbursements, of which $1.9 million offset our research and development spending and $0.3 million reduced our general and administrative spending incurred by Stirling. Funds received from ITI in excess of amounts earned are included in accrued expenses and other current liabilities, the balance of which was $7.1 million as of March 31, 2005.

(10) 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:

	Three Months Ended March 31,	
(in thousands)	**2005**	**2004**
Service cost	$ 68	$ 454
Interest cost	153	52
Expected return on plan assets	(90)	(46)
Realized losses	11	6
Net periodic benefit cost	$ 142	$ 466

(11) 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, the latter of which amounted to $4.3 million, net of the ITI funding of $1.9 million (Note 9), and $3.6 million for the three months ended March 31, 2005 and 2004, respectively. Total assets in the area of cardiology, which are included in Corporate and Other in the tables below, amounted to $57.3 million at March 31, 2005 and $8.6 million at December 31, 2004.

We evaluate performance of our operating segments based on revenue and operating income (loss). Segment information for the three months ended March 31, 2005 and 2004 is as follows:

(in thousands)	Consumer Diagnostic Products	Vitamins and Nutritional Supplements	Professional Diagnostic Products (restated)	Corporate and Other	Total (restated)
Three Months Ended March 31, 2005					
Net revenue to external customers	$ 43,420	$ 16,921	$ 31,579	$	$ 91,920
Operating income (loss)	6,941	(1,860)	(2,479)	(8,790)	(6,188)
Assets	246,534	51,241	311,961	62,947	672,683
At December 31, 2004					
Assets	243,001	48,072	264,260	12,936	568,269
Three Months Ended March 31, 2004					
Net revenue to external customers	40,418	20,291	30,399		91,108
Operating income (loss)	3,578	(30)	3,651	(3,096)	4,103

(12) Material Contingencies and Legal Settlements

Our material pending legal proceedings are described in the section of our annual report on Form 10-K for the year ended December 31, 2004 titled Item 3. Legal Proceedings. Material developments in our material pending legal proceedings are described in this quarterly report on Form 10-Q in Part II. Item 1. Legal Proceedings.

On February 2, 2005, our IMN subsidiary received $8.4 million representing its pro rata share of the net funds which were disbursed in connection with the settlement of class action suits against several raw material suppliers. The class action suits alleged that certain defendants unlawfully agreed to fix prices of certain vitamin products sold in the United States. IMN s recovery represented 7.3% of its approved purchases from the settling parties during the period in which the price fixing was alleged. The $8.4 million is included in other income, net, in the accompanying consolidated statement of operations for the three months ended March 31, 2005.

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On April 6, 2005, we entered into a binding settlement agreement of our pending litigation with Princeton BioMeditech Corporation (PBM) pursuant to which we paid $2.5 million in resolution of all pending litigation with PBM. PBM also received an option to permanently settle certain claims against our subsidiary, Applied Biotech, Inc. (ABI), that are not part of any pending case in exchange for $1.75 million of collaborative research and development funding from us. In connection with the settlement, the parties also entered into an agreement to form a joint venture pursuant to which both companies will make all their sales of existing drugs of abuse products (excluding sales to hospitals) (the New Joint Venture). All products sold by the New Joint Venture will be manufactured by PBM. The New Joint Venture will be owned equally by PBM and us and profits will be distributed in proportion to the trailing 12 month sales of products contributed to the venture. In connection with this settlement arrangement, we recorded a $4.2 million charge which is included in other income, net, in the accompanying consolidated statement of operations for the three months ended March 31, 2005.

On April 27, 2005 we entered into a settlement agreement with Quidel Corporation (Quidel) terminating all domestic and international intellectual property litigation with them. Under the settlement agreement, we received a net payment of $17.0 million and net future royalties from Quidel at 8.5%, in exchange for a license to all of our current and future patents which embody lateral flow technology for all diagnostic products other than for cardiology testing and for consumer/over-the-counter women s health (except that diagnostics for women s infectious diseases are within the licensed field of use). Quidel and its affiliates are granting a net royalty free cross-license of their current and future patents that embody lateral flow technology to us and all of our affiliates for all applications. The payment of $17.0 million will be included in our financial results for the three months ended June 30, 2005.

(13) Recent accounting pronouncements

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs, An Amendment of ARB No. 43, Chapter 4*. SFAS No. 151 clarifies that abnormal amounts of idle facility expense, freight, handling costs and wasted materials should be recognized as current period charges in all circumstances. We are required to adopt SFAS No. 151 on January 1, 2006. We do not expect the adoption of SFAS No. 151 to have a material impact on our consolidated financial statements.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment,* or SFAS No. 123R. SFAS No. 123R 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. It eliminates the ability to account for share-based compensation transactions using APB Opinion No. 25 and generally requires that such transactions be accounted for using a fair-value-based method. As permitted by the current SFAS No. 123, we have been accounting for share-based compensation to employees using APB Opinion No. 25 s intrinsic value method and, as such, we generally recognize no compensation cost for employee stock options. Under the original guidance of SFAS No. 123R, 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 are allowed to adopt the provisions of SFAS No. 123R at the beginning of their fiscal year that begins after June 15, 2005. Consequently, we will adopt SFAS No. 123R on January 1, 2006. We expect that the requirement to expense stock options and other equity interests that have been or will be granted pursuant to our equity incentive program will significantly increase our operating expenses and result in lower earnings per share. See note 5 of these consolidated financial statements for the effect of accounting for stock-based compensation using the fair-value-based method. The adoption of SFAS No. 123R will have no impact on our cash flows.

In December 2004, the FASB issued SFAS No. 153, *Exchange of Nonmonetary Assets, an Amendment of APB Opinion No. 29, Accounting for Nonmonetary Transactions.* SFAS No. 153 is based on the principle that exchange of nonmonetary assets should be measured based on the fair market value of the assets exchanged. SFAS No. 153 eliminates the exception of nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. SFAS 153 is effective for nonmonetary asset exchanges in fiscal periods beginning after June 15, 2005. We are currently evaluating the provisions of SFAS No. 153 and do not believe that the adoption of SFAS No. 153 will have a material impact on our consolidated financial statements.

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(14) Guarantor Financial Information

We issued $150.0 million in senior subordinated notes (the Bonds) to qualified institutional buyers in reliance on Rule 144A under the Securities Act of 1933, as amended (the Securities Act), and outside the United States in compliance with Regulation S of the Securities Act. Our payment obligations under the Bonds are currently guaranteed by all of our domestic subsidiaries (the Guarantor Subsidiaries). The guarantee is full and unconditional. Separate financial statements of the Guarantor Subsidiaries are not presented because we have determined that they would not be material to investors in the Bonds. The following supplemental financial information sets forth, on a consolidating basis, the statements of operations and cash flows for the three months ended March 31, 2005 and 2004 and the balance sheets as of March 31, 2005 and December 31, 2004 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.

On October 20, 2004, our subsidiary IMN became a Guarantor Subsidiary under the Bonds. Prior to this change, IMN was a Non-Guarantor Subsidiary. For comparative purposes, we have included the financial results of IMN in the results of the Guarantor Subsidiaries in the following supplemental financial information for all periods presented.

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF OPERATIONS

For the Three Months Ended March 31, 2005

(restated)

(in thousands)

unaudited

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	$ 5,478	$ 51,086	$ 45,339	$ (12,204)	$ 89,699
License revenue		31	2,190		2,221
Net revenue	5,478	51,117	47,529	(12,204)	91,920
Cost of sales	5,617	43,048	24,564	(13,498)	59,731
Gross profit	(139)	8,069	22,965	1,294	32,189
Operating expenses:					
Research and development	141	1,115	5,976		7,232

Sales and marketing	480	7,177	9,373		17,030
General and administrative	3,308	3,622	7,185		14,115
Total operating expenses	3,929	11,914	22,534		38,377
Operating (loss) income	(4,068)	(3,845)	431	1,294	(6,188)
Equity in earnings of subsidiaries, net of tax	3,907			(3,907)	
Interest expense, including amortization of discounts and write off of deferred financing costs	(4,245)	(484)	(1,343)	1,060	(5,012)
Other (expense) income, net	(3,074)	8,660	324	(999)	4,911
(Loss) income before income taxes	(7,480)	4,331	(588)	(2,552)	(6,289)
Income tax provision	322	718	473		1,513
Net (loss) income	$ (7,802)	$ 3,613	$ (1,061)	$ (2,552)	$ (7,802)

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF OPERATIONS

For the Three Months Ended March 31, 2004

(restated)

(in thousands)

(unaudited)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	$ 4,775	$ 50,481	$ 44,198	$ (10,846)	$ 88,608
License revenue		22	2,478		2,500
Net revenue	4,775	50,503	46,676	(12,327)	91,108
Cost of sales	5,044	38,414	21,776	(11,323)	53,911
Gross profit	(269)	12,089	24,900	477	37,197
Operating expenses:					
Research and development	96	628	6,699		7,423
Sales and marketing	471	6,597	7,283		14,351
General and administrative	2,315	3,544	5,461		11,320
Total operating expenses	2,882	10,769	19,443		33,094
Operating (loss) income	(3,151)	1,320	5,457	477	4,103
Equity in earnings of subsidiaries, net of tax	1,252			(1,252)	
Interest expense, including amortization of discounts and write off of deferred financing costs	(3,173)	(3,934)	(1,304)	641	(7,770)
Other income (expense), net	731	150	207	(641)	447
(Loss) income before income taxes	(4,341)	(2,464)	4,360	(775)	(3,220)
Income tax (benefit) provision	(958)	185	936		163
Net (loss) income	$ (3,383)	$ (2,649)	$ 3,424	$ (775)	$ (3,383)

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING BALANCE SHEET

March 31, 2005

(restated)

(in thousands)

(unaudited)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
ASSETS					
Current Assets:					
Cash and cash equivalents	$ 284	$ 11,213	$ 22,170	$	$ 33,667
Accounts receivable, net of allowances	1,934	36,548	19,332		57,814
Inventories	5,830	44,297	21,104	(4,718)	66,513
Deferred tax assets		142	2,819		2,961
Prepaid expenses and other current assets	2,135	3,585	8,408		14,128
Intercompany receivables	55,613	18,545	15,886	(90,044)	
Total current assets	65,796	114,330	89,719	(94,762)	175,083
Property, plant and equipment, net	2,858	30,173	36,213		69,244
Goodwill	55,250	109,116	94,520		258,886
Other intangible assets with indefinite lives	5,000	12,420	37,936		55,356
Core technology and patents, net	31,454	5,871	31,215		68,540
Other intangible assets, net	5,000	19,950	10,495		35,445
Deferred financing costs, net, and other non-current assets	6,524	1,751	1,060		9,335
Deferred tax assets			748	46	794
Investment in subsidiaries	273,704	(1,020)		(272,684)	
Intercompany notes receivable	95,425	15,089	2	(110,516)	
Total assets	$ 541,011	$ 307,680	$ 301,908	$ (477,916)	$ 672,683
LIABILITIES AND STOCKHOLDERS EQUITY					
Current liabilities:					
Current portion of long-term debt	$	$	$ 329	$	$ 329
Current portion of capital lease obligations		486	6		492
Accounts payable	2,775	22,978	13,718		39,471
Accrued expenses and other current liabilities	14,050	21,076	31,210		66,336
Intercompany payables	17,835	21,595	50,614	(90,044)	
Total current liabilities	34,660	66,135	95,877	(90,044)	106,628

Long-term liabilities:					
Long-term debt, net of current portion	169,306	20,000	22,009		211,315
Capital lease obligations, net of current portion		1,310	2		1,312
Deferred tax liabilities	17,064	4,401	7,261		28,726
Other long-term liabilities		29	4,692		4,721
Intercompany notes payable		53,221	57,295	(110,516)	
Total long-term liabilities	186,370	78,961	91,259	(110,516)	246,074
Stockholders equity	319,981	162,584	114,772	(277,356)	319,981
Total liabilities and stockholders equity	$ 541,011	$ 307,680	$ 301,908	$ (477,916)	$ 672,683

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING BALANCE SHEET

December 31, 2004

(restated)

(in thousands)

(unaudited)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
ASSETS					
Current Assets:					
Cash and cash equivalents	$ 12	$ 3,551	$ 13,193	$	$ 16,756
Accounts receivable, net of allowances	2,660	36,273	22,414		61,347
Inventories	6,340	41,152	19,815	(6,073)	61,234
Deferred tax assets			2,819		2,819
Prepaid expenses and other current assets	1,278	2,034	6,289		9,601
Intercompany receivables	54,358	10,015	14,145	(78,518)	
Total current assets	64,648	93,025	78,675	(84,591)	151,757
Property, plant and equipment, net	2,808	27,591	36,381		66,780
Goodwill	17,672	108,842	94,641		221,155
Other intangible assets with indefinite lives		12,420	38,122		50,542
Core technology and patents, net	2,533	6,009	31,785		40,327
Other intangible assets, net		20,522	7,158		27,680
Deferred financing costs, net, and other non-current assets	6,452	1,710	994		9,156
Deferred tax assets			826	46	872
Investment in subsidiaries	261,274	(966)		(260,308)	
Intercompany notes receivable	114,439	15,089		(129,528)	
Total assets	$ 469,826	$ 284,242	$ 288,582	$ (474,381)	$ 568,269
LIABILITIES AND STOCKHOLDERS EQUITY					
Current liabilities:					
Current portion of long-term debt	$	$	$ 88		$ 88
Current portion of capital lease obligations		461	6		467
Accounts payable	1,754	19,497	11,094		32,345
Accrued expenses and other current liabilities	12,408	21,654	22,180		56,242
Intercompany payables	13,640	15,964	48,914	(78,518)	
Total current liabilities	27,802	57,576	82,282	(78,518)	89,142
Long-term liabilities:					
Long-term debt, net of current portion	169,256	20,000	12		189,268

Capital lease obligations, net of current portion		1,397	4		1,401
Deferred tax liabilities	1,352	3,821	7,423		12,596
Other long-term liabilities		29	4,417		4,446
Intercompany notes payable		53,221	76,307	(129,528)	
Total long-term liabilities	170,608	78,468	88,163	(129,528)	207,711
Stockholders equity	271,916	148,198	118,137	(266,335)	271,416
Total liabilities and stockholders equity	$ 469,826	$ 284,242	$ 288,582	$ (474,381)	$ 568,269

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF CASH FLOWS

For the Three Months Ended March 31, 2005

(restated)

(in thousands)

(unaudited)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Operating Activities:					
Net (loss) income	$ (7,802)	$ 3,613	$ (1,061)	$ (2,552)	$ (7,802)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:					
Equity in earnings of subsidiaries, net of tax	(3,907)			3,907	
Interest expense related to amortization and/or write-off of noncash original issue discount and deferred financing costs	292	96	55		443
Depreciation and amortization	304	2,285	3,613		6,202
Deferred income taxes	112	526			638
Other noncash items	(25)	(6)	(37)		(68)
Minority interest in subsidiary			207		207
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net	726	5,079	2,883		8,688
Inventories	510	(557)	(1,595)	(1,355)	(2,997)
Prepaid expenses and other current assets	(857)	(640)	(2,979)		(4,476)
Intercompany payables or receivables	5,790	(2,900)	(3,304)	414	
Accounts payable	1,098	1,329	2,921		5,348
Accrued expenses and other current liabilities	289	(1,259)	10,018		9,048
Other non-current liabilities			76		76
Net cash (used in) provided by operating activities	(3,470)	7,566	10,797	414	15,307

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF CASH FLOWS (CONTINUED)

For the Three Months Ended March 31, 2005

(restated)

(in thousands)

(unaudited)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Investing Activities:					
Purchases of property, plant and equipment	(275)	(1,342)	(2,362)		(3,979)
Proceeds from sale of property, plant and equipment		6	37		43
Payments for acquisitions and of transactional costs for previous acquisitions	(12,492)	1,671	(4,955)		(15,776)
(Increase) decrease in other assets	(231)	37	(200)		(394)
Net cash (used in) provided by investing activities	(12,998)	372	(7,480)		(20,106)
Cash Flows from Financing Activities:					
Cash paid for financing costs	(82)	(163)	(110)		(355)
Proceeds from issuance of common stock, net of issuance costs	899				899
Net (repayment) borrowings under revolving line of credit	(77)		22,247		22,170
Repayments of notes payable			(9)		(9)
Principal payments of capital lease obligations		(113)	(2)		(115)
Intercompany notes payable (receivable)	16,000		(16,000)		
Net cash provided by (used in) financing activities	16,740	(276)	6,126		22,590
Foreign exchange effect on cash and cash equivalents			(466)	(414)	(880)
Net increase in cash and cash equivalents	272	7,662	8,977		16,911
Cash and cash equivalents, beginning of period	12	3,551	13,193		16,756
Cash and cash equivalents, end of period	$ 284	$ 11,213	$ 22,170	$	$ 33,667

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF CASH FLOWS

For the Three Months Ended March 31, 2004

(restated)

(in thousands)

(unaudited)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Operating Activities:					
Net (loss) income	$ (3,383)	$ (2,649)	$ 3,424	$ (775)	$ (3,383)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:					
Equity in earnings of subsidiaries, net of tax	(1,252)			1,252	
Interest expense related to amortization and/or write-off of noncash original issue discount and deferred financing costs	268	2,747	296		3,311
Noncash charge related to interest rate swap agreement	64				64
Depreciation and amortization	618	1,838	3,119		5,575
Deferred income taxes	(963)	262			(701)
Other noncash items			(19)		(19)
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net	1,167	1,560	(2,704)		23
Inventories	(1,023)	(343)	(1,479)	(477)	(3,322)
Prepaid expenses and other current assets	(185)	(187)	968		596
Intercompany payables or receivables	(498)	2,636	(2,403)	265	
Accounts payable	(2,696)	(1,668)	(1,456)		(5,820)
Accrued expenses and other current liabilities	1,457	(2,192)	2,698		1,963
Net cash (used in) provided by operating activities	(6,426)	2,004	2,444	265	(1,713)

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF CASH FLOWS (CONTINUED)

For the Three Months Ended March 31, 2004

(restated)

(in thousands)

(unaudited)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Investing Activities:					
Purchases of property, plant and equipment	(222)	(1,611)	(2,568)		(4,401)
Proceeds from sale of property, plant and equipment			28		28
Payments of transactional costs for previous acquisitions	(2,093)	(220)	(51)		(2,364)
Increase in other assets	(467)	(87)	(261)		(815)
Net cash used in investing activities	(2,782)	(1,918)	(2,852)		(7,552)
Cash Flows from Financing Activities:					
Cash paid for financing costs	(4,666)				(4,666)
Proceeds from issuance of common stock, net of issuance costs	521				521
Proceeds from issuance of senior subordinated notes	150,000				150,000
Net repayment under revolving line of credit		(17,588)	(22,872)		(40,460)
Repayments of notes payable	(9,000)	(75,304)	(9,937)		(94,241)
Principal payments of capital lease obligations		(105)	(2)		(107)
Intercompany notes (payables) or receivables	(124,809)	91,949	32,860		
Net cash provided by (used in) financing activities	12,046	(1,048)	49		11,047
Foreign exchange effect on cash and cash equivalents			3	(265)	(262)
Net increase (decrease) in cash and cash equivalents	2,838	(962)	(356)		1,520
Cash and cash equivalents, beginning of period	1,708	11,315	11,599		24,622
Cash and cash equivalents, end of period	$ 4,546	$ 10,353	$ 11,243		$ 26,142

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

Forward-Looking Statements

As noted above, this quarterly report on Form 10-Q, including this Item 2, 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. Forward-looking statements in this Item 2 include, without limitation, statements regarding our expectations with respect to benefits to be realized as a result of synergies relating to our acquisitions, net product sales, our funding plans for our future working capital needs and commitments, and the impact of our acquisitions. Actual results or developments could differ materially from those projected in such statements as a result of numerous factors, including, without limitation, those risks and uncertainties set forth below under Certain Factors Affecting Future Results and Special Statement Regarding Forward-Looking Statements. The following discussion and analysis of our financial condition and results of operations should be read in light of those risks and uncertainties and in conjunction with our accompanying consolidated financial statements and notes thereto.

Restatement

On June 28, 2005, we announced that certain of our previously issued financial statements must be restated because they contain errors under accounting principles generally accepted in the United States (GAAP) relating to the recognition of revenue at one of our diagnostic divisions. We had determined that certain customers of this division were provided return or exchange rights in connection with the sale of certain products for which reliable estimates of returns or exchange had not been made, as a result of which the revenues associated with these sales should not have been recognized upon shipment to the customers under GAAP. Since that time the Audit Committee of our Board of Directors conducted an investigation into these matters using independent special counsel. The results of this investigation contributed to our determination that the necessary restatement required an aggregate increase of $0.7 million in net revenue with an impact of increasing gross profit and decreasing our net loss by an aggregate $0.6 million in the combined first quarters of 2005 and 2004.

Financial Overview

For the three months ended March 31, 2005, we recorded net revenue of $91.9 million, compared to $91.1 million for the three months ended March 31, 2004. Adjusted for the favorable impact of currency translation, net revenue for the first quarter of 2005 was essentially consistent with that for the first quarter of 2004. Our combined consumer and professional diagnostics businesses enjoyed a 5% growth, adjusted for the impact of currency translation, while this growth was offset by the decline in our vitamins and nutritional supplements business.

For the three months ended March 31, 2005, we incurred a net loss of $7.8 million, compared to a net loss of $3.4 million for the three months ended March 31, 2004. The significant loss for the first quarter of 2005, compared to the first quarter of 2004, resulted from: (i) a $1.6 million negative impact on gross profit due to a recall of two of our drugs of abuse diagnostic products following our decision to withdraw the products 510(k)s, (ii) margin deterioration in our vitamins and nutritional supplements business which affected our gross profit by $1.5 million, (iii) increased sales and marketing spending of $1.9 million, (iv) increased legal spending of $2.1 million due to our continued aggressive defense and enforcement of our intellectual property, (v) an increase of $1.2 million in operating expenses due to acquisitions, and (vi) a $4.3 million legal settlement with Princeton BioMeditech Corporation, or PBM. The negative impacts on the first quarter of 2005 financial results were

offset by an $8.4 million gain from a legal settlement of class action suits against several raw material suppliers in our vitamins and nutritional supplements business. In addition, we recently announced a settlement with Quidel Corporation, or Quidel, in which Quidel agreed to pay us net, $17.0 million for a license to our intellectual property for past product sales and an ongoing net royalty of 8.5% on future sales of their lateral flow products. The payment of $17.0 million from Quidel will be included in our results for the second quarter of 2005.

As a leading global developer of advanced diagnostic devices, we are continually exploring opportunities in a variety of professional diagnostic and consumer-oriented applications, including immuno-diagnostics with a focus on women s health, cardiology and infectious disease. Our emphasis on new product development requires substantial investment and involves significant inherent risk. We intend to continue to devote substantial resources to research and development activities. Our recently announced co-development agreement with ITI Scotland Ltd., or ITI Scotland, who will provide us with $56.5 million over three years to fund certain new and existing cardiovascular-related research and development initiatives, as well as development of our new cardiac center in Stirling, Scotland, is evidence of this commitment. In addition, we will continue to aggressively defend our substantial intellectual property portfolio, which underlies our emphasis on new product development, against potential infringers.

Our Acquisition of the Rapid Diagnostics Business from Abbott Laboratories

On September 30, 2003, we acquired the rapid diagnostics business of Abbott Laboratories, consisting of Abbott s lines of consumer diagnostic pregnancy tests, sold under the brand name Fact plus, and its professional rapid diagnostics products for various testing needs, including strep throat, pregnancy and drugs of abuse, which are sold under brand names Signify and TestPack. This acquisition resulted in a significant amount of goodwill. Goodwill represents the premium paid in excess of the identifiable assets of the business acquired. Goodwill can arise as a result of acquired going concern value, employees and synergies. Because of the unique way in which the acquisition was structured, access to the factors required for maintaining the continuity of the business was achieved through contractual arrangements with terms of up to two years to facilitate the rapid integration of the Abbott business into our infrastructure with minimal restructuring or exit costs required. For this reason, the vast majority of the purchase price was allocated to goodwill attributable to synergies arising from the application of our existing infrastructure to the operations and the brands of the acquired business. The acquisition was also attractive because of the similarity in mode of operation between the acquired products and our existing products.

In ultimately agreeing to pay the purchase price, our investment rationale focused specifically on (i) significant operating and marketing synergies that we believed would result in cost savings and therefore increased profits on a combined basis and (ii) strategic revenue and market growth objectives. We expected that the operating synergies would be achieved by adding the Fact plus volumes not currently manufactured by us and by taking over from other third party manufacturers and Abbott the manufacturing of the Signify and TestPack products. We believed that these benefits would arise both from efficiencies related to increased volume but also in part from the redesign of the products. We expected that the marketing synergies would arise as we leveraged our existing sales staff by adding Fact plus to our existing consumer diagnostics distribution capability.

With respect to marketing synergies, we have enjoyed the savings that we anticipated at the time of the acquisition with respect to the addition of the Fact plus product line to our existing consumer diagnostics business, which has sold and distributed Fact plus with nominal increases in consumer sales and marketing infrastructure. These marketing synergies benefited sales and marketing expense as a percentage of net product sales by 23 basis points for the three months ended March 31, 2005.

With respect to manufacturing synergies, since the second half of 2004, we have transitioned all of the manufacturing of the Signify products from a third party manufacturer to our own manufacturing facilities. This transition was part of the original plan at the date of acquisition and resulted in increased gross profit of approximately $1.4 million on Signify product sales since the second half of 2004, as compared to the margins prior to the second half of 2004.

Other manufacturing synergies anticipated at the time of the acquisition include the transition of the TestPack products to our product design and manufacturing capacity. This product transition is currently underway and is anticipated to be completed late in the second quarter of 2005 for all countries except Japan, where the transition will occur in the fourth quarter of 2005. We currently anticipate achieving synergies in line with our expectations as of the date of acquisition. Additional manufacturing synergies were anticipated as we transition production of Fact plus for the international market to our own manufacturing operations. We began this transition by taking over production of Fact plus made for sale to one very small target market in the second quarter of 2004 and we transitioned the vast majority of production of the pregnancy tests acquired from Abbott for the international markets in the fourth quarter of 2004 which, along with improved pricing due to distribution changes, resulted in a 12% increase in overall gross profit earned from Fact plus and international pregnancy sales in the fourth quarter of 2004 as compared to the third quarter of 2004. We expect the overall margins of Fact plus and international pregnancy sales going forward to be in line with that of the fourth quarter of 2004. Benefits that may arise from synergies between combined businesses, including the benefits arising out of synergies relating to our acquisition of the rapid diagnostics business from Abbott, are subject to the risks relating to our acquisitions, as well as the other numerous risks that our business faces set forth in the sections of this report entitled Certain Factors Affecting Future Results and Special Statement Regarding Forward-Looking Statements.

Results of Operations

Net Product Sales, Total and by Business Segment. Total net product sales increased by $1.1 million, or 1%, to $89.7 million for the three months ended March 31, 2005 from $88.6 million for the three months ended March 31, 2004. Excluding the favorable impact of currency translation, net product sales for the three months ended March 31, 2005 increased by $0.1 million, compared to the three months ended March 31, 2004. Net product sales by business segment for the three months ended March 31, 2005 and 2004 are as follows:

(in thousands)	Three Months ended March 31, 2005	2004 (restated)	% Change

Consumer diagnostic products	$	41,935	$	38,750	8%
Vitamins and nutritional supplements		16,921		20,290	(17)%
Professional diagnostic products		30,843		29,568	4%
Total net product sales	$	89,699	$	88,608	1%

Adjusted for currency translation impact, net product sales of our consumer diagnostic products increased by $2.5 million, or 6%, comparing the three months ended March 31, 2005 to the three months ended March 31, 2004. This increase represents organic growth in our premium pregnancy test products.

Comparing the three months ended March 31, 2005 to the three months ended March 31, 2004, our vitamins and nutritional supplements business declined by $3.4 million, or 17%, of which approximately $1.7 million resulted from a decline in sales of vitamin E due to its recent negative publicity in the industry. The remaining decrease in net product sales of our vitamins and nutritional supplements business resulted from competition due to continued excess capacity in the industry.

Adjusted for currency translation impact, net product sales of our professional diagnostic products increased by $1.0 million, or 4%, comparing the three months ended March 31, 2005 to the three months ended March 31, 2004. Acquisitions, primarily Viva Diagnostika, or Viva, in June 2004, contributed $2.7 million of net product sales of our professional diagnostic products for the three months ended March 31, 2005. Excluding the impact from currency translation and acquisitions, net product sales of our professional diagnostic products decreased by $1.7 million, comparing the three months ended March 31, 2005 to the three months ended March 31, 2004. The decline in sales of our professional diagnostic products primarily resulted from decreased sales of certain of our drugs of abuse diagnostic products due to an FDA issue at our subsidiary Applied Biotech, Inc., or ABI. See detailed discussion of the FDA issue at ABI in the risk factor entitled Our failure to meet strict regulatory requirements could require us to pay fines, incur other costs or even close our facilities in the section entitled Certain Factors Affecting Future Results included herein. In addition, during the first quarter of 2005, we recorded a $0.3 million specific returns reserve, which reduced our net product sales, due to a recall of two of our drugs of abuse diagnostic products following our decision to withdraw the products 510(k)s. The products impacted by the recall contributed approximately 1% of our net revenues in 2004. We believe that our recently executed joint venture agreement with PBM related to drugs of abuse diagnostic products should to a great extent replace these recalled products.

License Revenue. License revenue represents license and royalty fees from intellectual property license agreements with third-parties. License revenue decreased by $0.3 million, or 12%, to $2.2 million for the three months ended March 31, 2005 from $2.5 million for the three months ended March 31, 2004. The decrease is a function of the net results of royalties collected under new licenses and a decrease in royalties under expired licenses.

Gross Profit and Margin. Gross profit decreased by $5.0 million, or 13%, to $32.2 million for the three months ended March 31, 2005 from $37.2 million for the three months ended March 31, 2004. Approximately $1.6 million of the decrease in gross profit represented provisions for returns and inventory reserve which were established as a result of our recall of the drugs of abuse diagnostic products. Further, gross profit decreased due to the continued decline in profitability of our private label nutritional supplements business as a result of continued excess capacity in the industry, which gross profit declined by $1.5 million, comparing the first quarter of 2005 to the first quarter of 2004. The decline in the value of the U.S. Dollar against the Euro and British Pounds Sterling adversely impacted gross profit of certain of our products manufactured at our European subsidiaries and sold in U.S. Dollars by $0.4 million. The remaining $1.5 million decrease in gross profit primarily resulted from product mix.

Overall gross margin for the three months ended March 31, 2005 was 35%, compared to 41% for the three months ended March 31, 2004. Excluding the effect of the provisions for returns and inventory reserve related to the recall of the drugs of abuse diagnostic products, aggregating $1.6 million, gross margin for the three months ended March 31, 2005 was 37%. The decline in profitability in our private label nutritional supplements business due to competitive pricing in the industry impacted gross margin by 163 basis points. The effect on gross margin due to the weakened U.S. Dollar against the Euro and British Pounds Sterling was 43 basis points. The remaining decrease in gross margin resulted from product mix.

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 revenue. Gross profit from total net product sales decreased by $4.5 million, or 13%, to $31.0 million for the three months ended March 31, 2005 from $35.5 million for the three months ended March 31, 2004. Gross profit from net product sales by business segment for the three months ended March 31, 2005 and 2004 are as follows:

	Three Months ended March 31,		**%**

(in thousands)	2005	2004 (restated)	Change
Consumer diagnostic products	$ 20,924	$ 21,275	(2)%
Vitamins and nutritional supplements	689	2,625	(74)%
Professional diagnostic products	9,350	11,612	(19)%
Total gross profit from net product sales	$ 30,964	$ 35,512	(13)%

Gross profit from our consumer diagnostic product sales decreased by $0.4 million, or 2%, comparing the first quarter of 2005 to the first quarter of 2004, which resulted from the adverse impact on gross profit of certain of our products manufactured at our European subsidiaries and sold in U.S. Dollars due to the decline in the value of the U.S. Dollar against the Euro and British Pounds Sterling. Gross margin from our consumer diagnostic product sales dropped to 50% for the three months ended March 31, 2005 from 55% for the three months ended March 31, 2004, of which decrease 95 basis point resulted from the weakened U.S. Dollar. The remaining decrease in gross margin from our consumer diagnostic product sales resulted from change in product mix.

Of the decrease of $1.9 million, or 74%, in gross profit from our vitamins and nutritional supplements net product sales, comparing the first quarter of 2005 to the first quarter of 2004, approximately $1.5 million resulted from the continued decline in profitability of our private label nutritional supplements business due to pricing competition and excess capacity, which also explained the decrease in gross margin of our nutritionals business to 4% for the three months ended March 31, 2005 from 13% for the three

months ended March 31, 2004. The remaining decrease in gross profit from our nutritionals business primarily resulted from the decrease in vitamin E sales, as discussed above.

Gross profit from our professional diagnostic product sales decreased by $2.3 million, or 19%, comparing the first quarter of 2005 to the first quarter of 2004. Excluding the $1.6 million impact to gross profit due to our recall of the drugs of abuse diagnostic products, gross profit from our professional diagnostic product sales decreased by $0.6 million or 5%. The remaining decrease in gross profit from our professional diagnostic product sales primarily resulted from a decrease in sales of our drugs of abuse diagnostic tests, as discussed above. Excluding the impact of the recall, gross margin from our professional diagnostic product sales was 35% for the three months ended March 31, 2005, compared to 39% for the three months ended March 31, 2004. The decrease in gross margin from our professional diagnostic product sales resulted from change in product mix.

Research and Development Expense. Research and development expense decreased by $0.2 million, or 3%, to $7.2 million for the three months ended March 31, 2005 from $7.4 million for the three months ended March 31, 2004. The amount of research and development expense for the first quarter of 2005, or $7.2 million, was offset by the funding of $1.9 million from ITI Scotland earned during the quarter. Excluding the ITI Scotland funding, research and development expenses increased by $1.7 million, comparing the first quarter of 2005 to the first quarter of 2004, which primarily resulted from increased spending in our research and development activities in the area of cardiology.

Sales and Marketing Expense. Sales and marketing expense increased by $2.6 million, or 18%, to $17.0 million for the three months ended March 31, 2005 from $14.4 million for the three months ended March 31, 2004. Approximately $1.2 million of the increase in sales and marketing expenses resulted from our significant advertising efforts to promote our premium consumer diagnostic products in the first quarter of 2005. Approximately $0.8 million of the increase in sales and marketing expenses resulted from acquisitions, primarily Viva, and the effect of the weakened U.S. Dollar on translation of sales and marketing expenses incurred by our foreign subsidiaries. The remaining increase in sales and marketing expenses of $0.6 million primarily resulted from our expanded sales and marketing infrastructure to support the anticipated growth in our point-of-care professional diagnostics business.

Sales and marketing expense as a percentage of net product sales increased to 19% for the three months ended March 31, 2005, compared to 16% for the three months ended March 31, 2004. The increase in sales and marketing expense as a percentage of net product sales primarily resulted from our investment in advertising efforts of our premium consumer diagnostic products and sales and marketing infrastructure to support our anticipated growth in the point-of-care professional diagnostics business.

General and Administrative Expense. General and administrative expense increased by $2.8 million, or 25%, to $14.1 million for the three months ended March 31, 2005 from $11.3 million for the three months ended March 31, 2004. Approximately $2.1 million of the increase in general and administrative expenses resulted from an increase in legal spending, due to our active pursuits and defenses in litigations, including our lawsuits and settlements with Quidel and PBM. The remaining increase in general and administrative expense primarily resulted from various acquisitions. Due to the factors discussed herein, general and administrative expense as a percentage of net revenue increased to 15% for the three months ended March 31, 2005 from 12% for the three months ended March 31, 2004.

Interest Expense. Interest expense includes interest charges, the write-off and amortization of deferred financing costs and the amortization of non-cash discounts associated with our debt issuances. Interest expense decreased by $2.8 million, or 36%, to $5.0 million for the three months ended March 31, 2005 from $7.8 million for the three months ended March 31, 2004. In the first quarter of 2004, we recorded a charge of $3.5 million representing the write-off of unamortized deferred financing costs and prepayment fees and penalties related to the repayment of borrowings under our primary senior credit facility and certain subordinated notes with the proceeds from our $150.0 million bond offering in February 2004. Excluding such charge, interest expense increased by $0.7 million, or 16%, comparing the three months ended March 31, 2005 to the three months ended March 31, 2004. Such increase was partially due to a higher average outstanding debt balance which was $202.3 million during the three months ended March 31, 2005, compared to $183.8 million during the three months ended March 31, 2004, as a result of borrowings to fund various acquisitions and operations. Additionally, the 8.75% interest rate on the $150.0 million bonds, together with its 50 basis points interest penalty during a portion of the first quarter of 2005 due to the late registration of the related exchange offer, increased our average cash interest rate to 9.0% for the three months ended March 31, 2005 from 8.2% for the three months ended March 31, 2004. The bonds, which are due in 2012, provide us with a long-term fixed rate on a significant portion of our indebtedness, as compared to the variable rates under our senior credit facility.

Other Income, Net. Other income, 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, net, are summarized as follows:

(in thousands)	Three Months ended March 31, 2005	2004	$ Change
Interest income	$ 238	$ 347	$ (109)
Foreign exchange gains (losses), net	185	34	151
Other	4,488	66	4,422
Total other income, net	$ 4,911	$ 447	$ 4,464

Included in other income for the three months ended March 31, 2005 was 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, the latter of which is further discussed in Part II. Item 1. Legal Proceedings.

Provision for Income Taxes. Provision for income taxes increased by $1.3 million, to $1.5 million for the three months ended March 31, 2005 from $0.2 million for the three months ended March 31, 2004. The effective tax rate was (23)% for the three months ended March 31, 2005, compared to (5)% for the three months ended March 31, 2004. The significant increase in the income tax provision related to the state income tax provision as a result of the $8.4 million legal settlement of the class action suits, as discussed above, and to foreign income tax provisions for various foreign subsidiaries.

Net Loss. We incurred a net loss of $7.8 million for the three months ended March 31, 2005, compared to a net loss of $3.4 million for the three months ended March 31, 2004. Net loss available to common stockholders for the three months ended March 31, 2005 was $7.8 million, or $0.37 per basic and diluted share. Net loss available to common stockholders for the three months ended March 31, 2004 was $4.1 million, or $0.22 per basic and diluted share, after taking into account charges for redemption interest and amortization of beneficial conversion feature related to our Series A redeemable convertible preferred stock which were fully converted in January 2004. The increase in net loss for the three months ended March 31, 2005, compared to the three months ended March 31, 2004, primarily resulted from the various factors as discussed above. See note 5 of the accompanying consolidated financial statements for the calculation of net loss per 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 recently executed co-development funding agreement with ITI Scotland will be adequate to fund our operations, including our outstanding debt and other commitments, as discussed below, for the next 12 months. In the long-run, we expect to fund our working capital needs and other commitments primarily through the co-development funding program with ITI Scotland and through our operating cash flow, because we expect to 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.

Additionally, on April 27, 2005, we settled our infringement lawsuit with Quidel, whereby Quidel agreed to pay us net, $17.0 million for a license to our intellectual property for past product sales and an ongoing net royalty of 8.5% on future sales of their lateral flow products. We expect to utilize the $17.0 million settlement payment in funding 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 Ischemia Technologies, Inc., or Ischemia, Binax, Inc., or Binax, and the rapid diagnostics business acquired from Abbott Laboratories 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 March 31, 2005, we had cash and cash equivalents of $33.7 million, a $16.9 million increase from December 31, 2004. We have funded our business through operating cash flows, proceeds from borrowings and the issuance of equity securities. During the three months ended March 31, 2005, we generated cash of $15.3 million from our operating activities, which primarily resulted from an $11.0 million funding from ITI Scotland and a net decrease in working capital, excluding the change in the cash balance, of $4.7 million, offset by a loss, adjusted for non-cash items, of $0.4 million. The decrease in working capital, excluding the change in the cash balance, primarily resulted from a significant decrease in the accounts receivable balance due to collections of sales from the fourth quarter of 2004, which was a higher sales quarter than the first quarter of 2005. Our non-equity financing activities, primarily borrowings under our primary senior credit facility, net of various debt repayments and financing costs, provided us with cash of $21.7 million during the three months ended March 31, 2005. In addition, we received $0.9 million in proceeds from the exercises of common stock options during the three months ended March 31, 2005.

During the three months ended March 31, 2005, we used cash of $20.1 million for investing activities which consisted of $15.8 million paid for transaction costs associated with previously acquired businesses and the acquisitions of the consumer pregnancy test business of Advanced Clinical Systems Pty Ltd in Australia, or ACS, Ischemia and Binax, $3.9 million in capital expenditures, net of proceeds from sales of equipment, and an increase in other non-current assets of $0.4 million. Fluctuations in foreign currencies negatively impacted our cash balance by $0.9 million during the three months ended March 31, 2005.

Investing Activities

During the three months ended March 31, 2005, we incurred $3.9 million in capital expenditures, net of proceeds from sales of equipment. Significant capital expenditures during the three months ended March 31, 2005 included leasehold improvements of $1.0 million in connection with upgrading one of our vitamins and nutritional supplements plants and machinery and leasehold improvements totaling $0.6 million in connection with the transition of the manufacturing of the Testpack product, which we acquired as part of the rapid diagnostics business from Abbott, to our facilities. The remaining capital expenditures during the three months ended March 31, 2005 were incurred for the purchase of additional or replacement equipment to support our organic growth and various research and development activities and to furnish our new facilities in China and Scotland.

On January 24, 2005, we acquired the consumer pregnancy test business of ACS for an aggregate purchase price of $4.95 million which consisted of $4.65 million in cash and $0.3 million in estimated direct acquisition costs. In acquiring the business, we obtained the rights to the Crystal Clear brand. Crystal Clear is the leading consumer pregnancy test in Australia and has a leading position in New Zealand.

On March 16, 2005, we acquired Ischemia, a privately held, venture-backed company that has developed, manufactures and markets the only FDA-cleared in vitro diagnostic test targeted on cardiac ischemia. The preliminary aggregate purchase price was $27.2 million, which consisted of 968,454 shares of our common stock with an aggregate fair value of $22.7 million, estimated exit costs of $1.7 million to vacate Ischemia s manufacturing and administrative facilities, estimated direct acquisition costs of $2.3 million and $0.5 million in assumed debt.

On March 31, 2005, we acquired Binax, a privately held developer, manufacturer and distributor of rapid diagnostic products for infectious disease testing, primarily related to the respiratory system. The preliminary aggregate purchase price was $44.7 million which consisted of $9.0 million in cash, 1,422,400 shares of our common stock with an aggregate fair value of $35.2 million and $0.5 million in estimated direct acquisition costs. The terms of the acquisition agreement also 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 next five years.

Financing Activities

On February 10, 2004, we completed the sale of $150.0 million of 8.75% senior subordinated notes, or bonds, due 2012 in a private placement to qualified institutional buyers. The proceeds from the bond issuance were used to repay certain of our then existing debt and provided us with additional funds for our operations. These bonds accrue interest from the date of their issuance, or February 10, 2004, at the rate of 8.75% per year. Interest on the bonds are payable semi-annually in arrears on each February 15 and August 15, which commenced on August 15, 2004. In addition, under the related registration rights agreement, we were to cause the registration statement with the Securities and Exchange Commission, or SEC, with respect to a registered exchange offer to exchange the notes underlying the bonds for new notes, to be declared effective under the Securities Act of 1933, as amended, within 240 days after the date of the bonds issuance and consummate the exchange offer within 270 days after the date of the bonds issuance. As we were unable to consummate the exchange offer until March 28, 2005, interest on the bonds increased by 0.25% point per year for the first 90-day period immediately following the default and an additional 0.25% point per year with respect to each subsequent 90-day period up to a maximum amount of additional interest of 1% point. Consequently, from October 7, 2004 through January 6, 2005, we

accrued interest on the bonds at a rate of 9% and from January 6, 2005 though March 27, 2005, we accrued interest on the bonds at a rate of 9.25%. As of March 31, 2005, accrued interest related to the bonds amounted to $1.7 million.

We may redeem the bonds, in whole or in part, at any time on or after February 15, 2008, at a redemption price equal to 100% of the principal amount plus a premium declining ratably to par, plus accrued and unpaid interest. In addition, prior to February 15, 2007, we may redeem up to 35% of the aggregate principal amount of the bonds issued with the proceeds of qualified equity offerings at a redemption price equal to 108.75% of the principal amount, plus accrued and unpaid interest. If we experience a change of control, we may be required to offer to purchase the bonds at a purchase price equal to 101% of the principal amount, plus accrued and unpaid interest. We might not be able to pay the required price for bonds presented to us at the time of a change of control because our primary senior credit facility or other indebtedness may prohibit payment or we might not have enough funds at that time.

The bonds are unsecured and are subordinated in right of payment to all of our existing and future senior debt, including our guarantee of all borrowings under our primary senior credit facility. The bonds are effectively subordinated to all existing and future liabilities, including trade payables, of those of our subsidiaries that do not guarantee the bonds.

The bonds are guaranteed by all of our domestic subsidiaries that are guarantors or borrowers under our primary senior credit facility. The guarantees are general unsecured obligations of the guarantors and are subordinated in right of payment to all existing and future senior debt of the applicable guarantors, which includes their guarantees of, and borrowings under our primary senior credit facility.

The indenture governing the bonds contains covenants that will limit our ability and the ability of our subsidiaries to, among other things, incur additional indebtedness in the aggregate, subject to our interest coverage ratio, pay dividends or make other distributions or repurchase or redeem our stock, make investments, sell assets, incur liens, enter into agreements restricting our subsidiaries ability to pay dividends, enter into transactions with affiliates and consolidate, merge or sell all or substantially all of our assets. These covenants are subject to certain exceptions and qualifications.

Our primary senior credit facility with a group of banks, as amended, currently provides us with revolving lines of credit in the aggregate amount of up to $50.0 million, subject to continuing covenant compliance. As of March 31, 2005, we had $42.0 million of outstanding borrowings under the revolving lines of credit.

We may repay any future borrowings under the revolving lines of credit at any time but in no event later than March 31, 2008. We are required to make mandatory prepayments under our primary senior credit facility if we meet certain cash flow thresholds, issue equity securities or subordinated debt, or sell assets not in the ordinary course of our business.

Borrowings under the revolving lines of credit bear interest at either (1) the London Interbank Offered Rate, or LIBOR, as defined in the credit agreement, plus applicable margins or, at our option, (2) a floating Index Rate, as defined in the credit 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 March 31, 2005, the applicable interest rate under the revolving lines of credit, including the applicable margin, ranged from 6.14% to 6.60%.

Borrowings under our primary senior credit facility are secured by the stock of our U.S. and European subsidiaries, substantially all of our intellectual property rights and the assets of our businesses in the U.S. and Europe, excluding those assets of Orgenics Ltd., our Israeli subsidiary, Inverness Medical Shanghai Co., Ltd., our subsidiary in China, Inverness Medical Australia Pty. Ltd., our Australian subsidiary, and Unipath Scandinavia AB, our Swedish subsidiary, and the stock of Orgenics and certain smaller subsidiaries. Under the senior credit agreement, as amended, we must comply with various financial and non-financial covenants. The primary financial covenants pertain to, among other things, fixed charge coverage ratio, capital expenditures, various leverage ratios, earnings before interest, taxes, depreciation and amortization, or EBITDA, and a minimum cash requirement. Additionally, the senior credit agreement currently prohibits us from paying dividends. We are currently in compliance with the covenants.

On September 20, 2002, we sold units having an aggregate purchase price of $20.0 million to private investors to help finance our acquisition of Wampole Laboratories. Each unit was issued for $50,000 and consisted of (1) a 10% subordinated promissory note in the principal amount of $50,000 and (2) a warrant to acquire 400 shares of our common stock at an exercise price of $13.54 per share. In the aggregate, we issued fully vested warrants to purchase 160,000 shares of our common stock, which may be exercised at any time on or prior to September 20, 2012. In addition, the placement agent for the offering of the units received a warrant to purchase 37,700 shares of our common stock, the terms of which are identical to the warrants sold as a part of the units. The 10% subordinated notes accrue interest on the outstanding principal amount at 10% per annum, which is payable quarterly in arrears on the first day of each calendar quarter, which started on October 1, 2002. The 10% subordinated notes mature on September 20, 2008, subject to acceleration in certain circumstances, and we may prepay the 10% subordinated notes at any time, subject to certain prepayment penalties and the consent of our senior lenders. Prepayments are made in cash or in shares of our common stock valued at 95% of the average closing price of such stock over the ten consecutive trading days immediately preceding the payment date. The 10%

subordinated notes are expressly subordinated to up to $150.0 million of indebtedness for borrowed money incurred or guaranteed by our company plus any other indebtedness that we incur to finance or refinance an acquisition. Among the purchasers of the units were three of our directors and officers and an entity controlled by our chief executive officer, who collectively purchased an aggregate of 37 units consisting of 10% subordinated notes in the aggregate principal amount of $1.85 million and warrants to purchase an aggregate of 14,800 shares of our common stock.

As of March 31, 2005, we had an aggregate of $2.1 million in outstanding capital lease obligations which are payable through 2009.

Income Taxes

As of December 31, 2004, we had approximately $108.7 million and $25.9 million of domestic and foreign net operating loss, or NOL, carryforwards, respectively, which either expire on various dates through 2024 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, 2004 included approximately $48.5 million of pre-acquisition losses from our subsidiaries, Inverness Medical Nutritionals Group, 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 noncurrent intangible assets related to the acquisitions, prior to reducing our income tax expense. Also included in our domestic NOL carryforwards at December 31, 2004 was approximately $1.8 million resulting from the exercise of employee stock options, the tax benefit of which, when recognized, will be accounted for as a credit to additional paid-in capital rather than a reduction of income tax. Furthermore, all domestic losses are subject to the Internal Revenue Service Code Section 382 limitation and may be limited in the event of certain cumulative changes in ownership interests of significant shareholders over a three-year period in excess of 50%. Section 382 imposes an annual limitation on the use of these losses to an amount equal to the value of the company at the time of the ownership change multiplied by the long term tax exempt rate. We have recorded a valuation allowance against a portion of the deferred tax assets related to our net operating losses and certain of our other deferred tax assets to reflect uncertainties that might affect the realization of such deferred tax assets, as these assets can only be realized via profitable operations.

Off-Balance Sheet Arrangements

We had no material off-balance sheet arrangements as of March 31, 2005.

Contractual Obligations

The following table summarizes our principal contractual obligations as of March 31, 2005 that have changed significantly since December 31, 2004 and the effects of 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, 2004 but omitted in the table below represent those that have not changed significantly since that date.

		Payments Due by Period			
Contractual Obligations	**Total**	**Remainder of 2005**	**2006 - 2007**	**2008 - 2009**	**Thereafter**

	(in thousands)				
Long-term debt obligations (1)	$ 212,338	$ 316	$ 22	$ 62,000	$ 150,000
Research and development spending commitment (2)	70,620	14,124	48,022	8,474	
Purchase obligations other (3)	26,436	26,436			
Contingent consideration (4)	12,500	1,500	11,000		

(1) Long-term debt obligations increased by $22.2 million since December 31, 2004 primarily due to our borrowings of $22.0 million under the lines of credit of our primary senior credit facility during the three months ended March 31, 2005.

(2) Represents our commitment of 37.5 million British Pounds Sterling to certain research and development programs under our co-development agreement with ITI Scotland. See Note 9 of the accompanying consolidated financial statements.

(3) Other purchase obligations relate to inventory purchases and other operating expense commitments. Other purchase obligations decreased by $8.7 million, as compared to the commitments at December 31, 2004, primarily due to our efforts to reduce our inventory levels of vitamin E and to maintain our overall inventory levels constant after a build-up of it last year to support anticipated organic growth.

(4) The increase in total contingent consideration of $11.0 million since December 31, 2004 represents our contingent payment arrangement with the Binax shareholders as part of our acquisition of Binax on March 31, 2005. The timing of such contingent payment, if any, as shown in the table above, is based on management s estimate. See note 8(a) of the accompanying consolidated financial statements.

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, 2004 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 revenues are 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 from Abbott Laboratories in September 2003, we entered into a transition services agreement with Abbott, whereby Abbott would continue to distribute the acquired products sold under the TestPack brand for a period of up to 18 months. During the transition period, we recognized revenue on sales of the TestPack products when title transferred from Abbott to third party customers.

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

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

Certain sales arrangements require us to accept product returns. From time to time, we also enter into sales incentive arrangements with our retail customers, which generally reduce the sale prices of our products. As a result, we must establish allowances for potential future product returns and claims resulting from our sales incentive arrangements against product revenue recognized in any reporting period. Calculation of these allowances requires significant judgments and estimates. When evaluating the adequacy of the sales returns and other allowances, our

management analyzes historical returns, current economic trends, and changes in customer and consumer demand and acceptance of our products. When such analysis is not available and a right of return exists, we record revenue when the right of return is no longer applicable. Material differences in the amount and timing of our product revenue for any reporting period may result if changes in conditions arise that would require management to make different judgments or utilize different estimates.

Our total provision for sales returns and other allowances related to sales incentive arrangements amounted to $13.4 million, or 13% of product sales, for both the three months ended March 31, 2005 and 2004, 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 $57.8 million and $61.3 million, net of allowances for doubtful accounts of $2.8 million and $2.4 million, as of March 31, 2005 and December 31, 2004, 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 $66.5 million and $61.2 million, net of a provision for excess and obsolete inventory of $5.6 million and $4.1 million, as of March 31, 2005 and December 31, 2004, respectively. Included in the provision for excess and obsolete inventory at March 31, 2005 was a $1.3 million specific reserve established during the first quarter of 2005 for certain drugs of abuse products in inventory, which products we recalled following our decision to withdraw the products 510(k)s.

Valuation of Goodwill and Other Long-Lived and Intangible Assets

Our long-lived assets include (1) property, plant and equipment, (2) goodwill and (3) other intangible assets. As of March 31, 2005, the balances of property, plant and equipment, goodwill and other intangible assets, net of accumulated depreciation and amortization, were $69.2 million, $258.9 million and $159.3 million, respectively.

Goodwill and other intangible assets are initially created as a result of business combinations or acquisitions of intellectual property. The values we record for goodwill and other intangible assets represent fair values calculated by accepted valuation methods. Such valuations require us to provide significant estimates and assumptions which are derived from information obtained from the management of the acquired businesses and our business plans for the acquired businesses or intellectual property. Critical estimates and assumptions used in the initial valuation of goodwill and other intangible assets include, but are not limited to: (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, Statement of Financial Accounting Standards, or 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 $86.1 million and $172.8 million, respectively, as of March 31, 2005. As of September 30, 2004, 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, 2004, 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, 2004, 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 March 31, 2005, future events could cause us to conclude otherwise.

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 $81.6 million as of December 31, 2004 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.

In October 2004, the American Jobs Creation Act of 2004, or the AJCA, was signed into law. The AJCA contains a series of provisions, several of which are pertinent to our company. The AJCA creates a temporary incentive for U.S. multinational corporations to repatriate accumulated income abroad by providing an 85% dividends received deduction for certain dividends from controlled foreign corporations. 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.

Legal Contingencies

In the section of this quarterly report on Form 10-Q titled Part II. Item 1. Legal Proceedings, we have reported on certain material pending legal proceedings. In addition, because of the nature of our business, we may from time to time be subject to commercial disputes, consumer product claims or various other lawsuits arising in the ordinary course of our business, and we expect this will continue to be the case in the future. These lawsuits generally seek damages, sometimes in substantial amounts, for commercial or personal injuries allegedly suffered and can include claims for punitive or other special damages. In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties, which can be expensive and can result in counterclaims against us.

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

Recently Issued Accounting Standards

In November 2004, the Financial Accounting Standards Board, or the FASB, issued SFAS No. 151, *Inventory Costs, An Amendment of ARB No. 43, Chapter 4*. SFAS No. 151 clarifies that abnormal amounts of idle facility expense, freight, handling costs and wasted materials should be recognized as current period charges in all circumstances. We are required to adopt SFAS No. 151 on

January 1, 2006. We do not expect the adoption of SFAS No. 151 to have a material impact on our financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment,* or SFAS No. 123R. SFAS No. 123R 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. It eliminates the ability to account for share-based compensation transactions using Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, and generally requires that such transactions be accounted for using a fair-value-based method. As permitted by the current SFAS No. 123, *Accounting for Stock-Based* Compensation, we have been accounting for share-based compensation to employees using APB Opinion No. 25 s intrinsic value method and, as such, we generally recognize no compensation cost for employee stock options. Under the original guidance of SFAS No. 123R, 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 are allowed to adopt the provisions of SFAS No. 123R at the beginning of their fiscal year that begins after June 15, 2005. Consequently, we elect to adopt SFAS No. 123R on January 1, 2006. We expect that the requirement to expense stock options and other equity interests that have been or will be granted pursuant to our equity incentive program will significantly increase our operating expenses and result in lower earnings per share. See note 5 of the accompanying consolidated financial statements for the effect of accounting for stock-based compensation using the fair-value-based method. The adoption of SFAS No. 123R will have no impact on our cash flows.

In December 2004, the FASB issued SFAS No. 153, *Exchange of Nonmonetary Assets, an Amendment of APB Opinion No. 29, Accounting for Nonmonetary Transactions.* SFAS No. 153 is based on the principle that exchange of nonmonetary assets should be measured based on the fair market value of the assets exchanged. SFAS No. 153 eliminates the exception of nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. SFAS No. 153 is effective for nonmonetary asset exchanges in fiscal periods beginning after June 15, 2005. We do not believe that the adoption of SFAS No. 153 will have a material impact on our financial position, results of operations or cash flows.

Certain Factors Affecting Future Results

The risk factors described below may materially impact your investment in our company or may in the future, and, in some cases already do, materially affect us and our business, financial condition and results of operations. You should carefully consider these factors with respect to your investment in our securities. This section includes or refers to certain forward-looking statements; you should read the explanation of the qualifications and limitations on such forward-looking statements beginning on pages 2, 23 and 46 of this report.

Our business has substantial indebtedness, which could, among other things, make it more difficult for us to satisfy our debt obligations, require us to use a large portion of our cash flow from operations to repay and service our debt or otherwise create liquidity problems, limit our flexibility to adjust to market conditions, place us at a competitive disadvantage and expose us to interest rate fluctuations.

We currently have, and we will likely continue to have, a substantial amount of indebtedness. As of March 31, 2005, we had approximately $214.4 million in aggregate principal indebtedness outstanding, of which $44.4 million is secured indebtedness, and $8 million of additional borrowing capacity under the revolving portions of our credit facilities. In addition, subject to restrictions in our credit facilities and the indenture governing our $150 million in outstanding 8.75% senior subordinated notes, or the senior subordinated notes, we may incur additional indebtedness. For the quarter ended March 31, 2005, and for the years ended December 31, 2004 and 2003, we recorded $5.0 million, $22.1 million and $9.7 million, respectively, of interest expense related to our indebtedness, which included $0.4 million, $4.2 million and $1.0 million, respectively, in non-cash interest primarily related to amortization of debt origination costs.

Our substantial indebtedness could affect our future operations in important ways. For example, it could:

make it more difficult to satisfy our obligations under the senior subordinated notes, our credit facilities and our other debt-related instruments;

require us to use a large portion of our cash flow from operations to pay principal and interest on our indebtedness, which would reduce the amount of cash available to finance our operations and other business activities and may require us, in order to meet our debt service obligations, to delay or reduce capital expenditures or the introduction of new products and/or forego business opportunities, including acquisitions, research and development projects or product design enhancements;

limit our flexibility to adjust to market conditions, leaving us vulnerable in a downturn in general economic conditions or in our business and less able to plan for, or react to, changes in our business and the industries in which we operate;

impair our ability to obtain additional financing;

place us at a competitive disadvantage compared to our competitors that have less debt; and

expose us to fluctuations in the interest rate environment with respect to our indebtedness that bears interest at variable rates.

We expect to obtain the money to pay our expenses and to pay the principal and interest on the senior subordinated notes, our senior credit facility and our other debt from cash flow from our operations and from additional loans under our senior credit facility, subject to continued covenant compliance. Our ability to meet our expenses thus depends on our future performance, which will be affected by financial, business, economic and other factors. We will not be able to control many of these factors, such as economic conditions in the markets in which we operate and pressure from competitors. We cannot be certain that our cash flow will be sufficient to allow us to pay principal and interest on our debt and meet our other obligations. If our cash flow and capital resources prove inadequate, we could face substantial liquidity problems and might be required to dispose of material assets or operations, restructure or refinance our debt, including the notes, seek additional equity capital or borrow more money. We cannot guarantee that we will be able to do so on terms acceptable to us. In addition, the terms of existing or future debt agreements, including the credit agreement governing our senior credit facility and the indenture governing the senior subordinated notes, may restrict us from adopting any of these alternatives.

We have entered into agreements governing our indebtedness that subject us to various restrictions that may limit our ability to pursue business opportunities.

The agreements governing our indebtedness, including the credit agreement governing our senior credit facility and the indenture governing the senior subordinated notes, subject us to various restrictions on our ability to engage in certain activities, including, among other things, our ability to:

incur additional indebtedness;

pay dividends or make distributions or repurchase or redeem our stock;

acquire other businesses;

make investments;

make loans to or extend credit for the benefit of third parties or our subsidiaries;

enter into transactions with affiliates;

raise additional capital;

make capital or finance lease expenditures;

dispose of or encumber assets; and

consolidate, merge or sell all or substantially all of our assets.

These restrictions may limit our ability to pursue business opportunities or strategies that we would otherwise consider to be in our best interests. In particular, all acquisitions of other businesses, other than very small acquisitions, will require us to obtain our lenders consent under our senior credit facility. We have been required to obtain, and have obtained, our lenders consent under our senior credit facility in order to complete our acquisitions of the Wampole Division of MedPointe Inc., or Wampole, Ostex International, Inc., or Ostex, Applied Biotech, Inc., or ABI, and the rapid diagnostics business that we acquired from Abbott Laboratories, or the Abbott rapid diagnostics business, Ischemia, Inc., or Ischemia, Binax, Inc., or Binax.

Our senior credit facilities contain certain financial covenants that we may not satisfy which, if not satisfied, could result in the acceleration of the amounts due thereunder our credit facilities and the limitation of our ability to borrow additional funds in the future.

As of March 31, 2005, we had approximately $42.0 million of indebtedness outstanding under our senior credit facility and approximately $8.0 million of additional borrowing capacity thereunder. The agreements governing this facility subject us to various financial and other covenants with which we must comply on an ongoing or periodic basis. These include covenants pertaining to fixed charge coverage, capital expenditures, various leverage ratios, minimum EBITDA and minimum cash requirements. If we violate any of these covenants, there may be a material adverse effect on us. Most notably, our outstanding debt under our senior credit facility could become immediately due and payable, our lenders could proceed against any collateral securing such indebtedness, and our ability to borrow additional funds in the future may be limited.

A default under any of our agreements governing our indebtedness could result in a default and acceleration of indebtedness under other agreements.

The agreements governing our indebtedness, including our senior credit facility and the indenture governing the senior subordinated notes, contain cross-default provisions whereby a default under one agreement could result in a default and acceleration of our repayment obligations under other agreements. If a cross-default were to occur, we may not be able to pay our debts or borrow sufficient funds to refinance them. Even if new financing were available, it may not be on commercially reasonable terms or terms that are acceptable to us. If some or all of our indebtedness is in default for any reason, our business, financial condition and results of operations could be materially and adversely affected.

We may not be able to satisfy our debt obligations upon a change of control, which could limit our opportunity to enter into a change of control transaction.

Upon the occurrence of a change of control, as defined in the indenture governing the senior subordinated notes, each holder of our senior subordinated notes will have the right to require us to purchase the notes at a price equal to 101% of the principal amount, together with any accrued and unpaid interest. Our failure to purchase, or give notice of purchase of, the senior subordinated notes would be a default under the indenture, which would in turn be a default under our senior credit facility. In addition, a change of control may constitute an event of default under our senior credit facility. A default under our senior credit facility would result in an event of default under our 10% subordinated notes and, if the lenders accelerate the debt under our senior credit facility, the indenture governing the senior subordinated notes, and may result in the acceleration of any of our other indebtedness outstanding at the time. As a result, if we do not have enough cash to repay all of our indebtedness or to repurchase all of the senior subordinated notes, we may be limited in the change of control transactions that we may pursue.

Our acquisitions may not be profitable, and the integration of these businesses may be costly and difficult and may cause disruption to our business.

We have, since commencing activities in November 2001, acquired and we have attempted to integrate, or we are in the process of integrating, into our operations Unipath Limited and its associated companies and assets, or the Unipath business, IVC Industries, Inc. (now doing business as Inverness Medical Nutritionals Group, or IMN), Wampole, Ostex, ABI, the Abbott rapid diagnostics business, Ischemia and Binax. We have also made a number of smaller acquisitions. The ultimate success of all of our acquisitions depends, in part, on our ability to realize the anticipated synergies, cost savings and growth opportunities from integrating these businesses or assets into our existing businesses. However, the successful integration of independent businesses or assets is a complex, costly and time-consuming process. The difficulties of integrating companies and acquired assets include among others:

consolidating manufacturing and research and development operations, where appropriate;

integrating newly acquired businesses or product lines into a uniform financial reporting system;

coordinating sales, distribution and marketing functions;

establishing or expanding manufacturing, sales, distribution and marketing functions in order to accommodate newly acquired businesses or product lines;

preserving the important licensing, research and development, manufacturing and supply, distribution, marketing, customer and other relationships;

minimizing the diversion of management s attention from ongoing business concerns; and

coordinating geographically separate organizations.

We may not accomplish the integration of our acquisitions smoothly or successfully. The diversion of the attention of our management from our current operations to the integration effort and any difficulties encountered in combining operations could prevent us from realizing the full benefits anticipated to result from these acquisitions and adversely affect our other businesses. Additionally, the costs associated with the integration of our acquisitions, including our costs associated with the integration of the operations of ABI, the Abbott rapid diagnostics business, Ischemia and Binax can be substantial. To the extent that we incur integration costs that are not anticipated when we finance our acquisitions, these unexpected costs could adversely impact our liquidity or force us to borrow additional funds. Ultimately, the value of any business or asset that we have acquired may not be greater than or equal to its purchase price.

If we choose to acquire or invest in new and complementary businesses, products or technologies instead of developing them ourselves, such acquisitions or investments could disrupt our business and, depending on how we finance these acquisitions or investments, could result in the use of significant amounts of cash.

Our success depends in part on our ability to continually enhance and broaden our product offerings in response to changing technologies, customer demands and competitive pressures. Accordingly, from time to time we may seek to acquire or invest in businesses, products or technologies instead of developing them ourselves. Acquisitions and investments involve numerous risks, including:

the inability to complete the acquisition or investment;

disruption of our ongoing businesses and diversion of management attention;

difficulties in integrating the acquired entities, products or technologies;

difficulties in operating the acquired business profitably;

difficulties in transitioning key customer, distributor and supplier relationships;

risks associated with entering markets in which we have no or limited prior experience; and

unanticipated costs.

In addition, any future acquisitions or investments may result in:

issuances of dilutive equity securities, which may be sold at a discount to market price;

use of significant amounts of cash;

the incurrence of debt;

the assumption of significant liabilities;

unfavorable financing terms;

large one-time expenses; and

the creation of certain intangible assets, including goodwill, the write-down of which may result in significant charges to earnings.

Any of these factors could materially harm our business or our operating results.

If goodwill and/or other intangible assets that we have recorded in connection with our acquisitions of other businesses become impaired, we could have to take significant charges against earnings.

In connection with the accounting for our acquisitions of the Unipath business, Wampole, Ostex, ABI, the Abbott rapid diagnostics product lines, Ischemia and Binax, we have recorded, or expect to record, a significant amount of goodwill and other intangible assets. Under current accounting guidelines, we must assess, at least annually and potentially more frequently, whether the value of goodwill and other intangible assets has been impaired. Any reduction or impairment of the value of goodwill or other

intangible assets will result in a charge against earnings which could materially adversely affect our reported results of operations in future periods.

We could experience significant manufacturing delays, disruptions to our ongoing research and development and increased production costs if Unilever is unable to successfully assign or sublease to us the lease for the multi-purpose facility that we currently use in Bedford, England.

One of our primary operating facilities is located in Bedford, England. The Bedford facility is a multi-purpose facility that is registered with the FDA, contains state-of-the-art research laboratories and is equipped with specialized manufacturing equipment. This facility currently provides the manufacturing for most of our Clearblue and Clearview products, serves as our primary research and development center and serves as the administrative center for our European operations. We also use this facility to manufacture the digital and non-digital e.p.t pregnancy tests for Pfizer in connection with our supply arrangements with Pfizer for these products. We are currently using the Bedford facility pursuant to our acquisition agreement with Unilever relating to our acquisition of the Unipath business in late 2001. Unilever currently leases this facility from a third party landlord. Pursuant to the terms of Unilever s lease, Unilever cannot assign the lease or sublet the Bedford facility to us without first obtaining the landlord s consent. The landlord has not yet consented to, and may not in the future consent to, an assignment of the lease or a sublease to us. The terms of our acquisition agreement obligate Unilever to provide to us the benefit of its lease of the Bedford facility. If Unilever is unable to successfully acquire such consent or otherwise enable us to realize the benefit of Unilever s lease of the Bedford facility, or if its lease is terminated, we may be forced to renegotiate a lease of the Bedford facility on substantially less favorable terms or seek alternative means of producing our products, conducting our research and housing our European administrative staff. In either case, we may experience increased production costs or manufacturing delays, which could prevent us from meeting contractual supply obligations or jeopardize important customer relationships. We may also suffer disruptions to our ongoing research and development while we are resolving these issues. We cannot assure you that we will be able to renegotiate a lease for the Bedford facility on terms that are acceptable to us or find an acceptable replacement for this facility. Any one or more of these events may have a material adverse effect on us.

We may experience manufacturing problems or delays, which could result in decreased revenues or increased costs.

Many of our manufacturing processes are complex and require specialized and expensive equipment. Replacement parts for our specialized equipment can be expensive and, in some cases, can require lead times of up to a year to acquire. In addition, our private label consumer diagnostic products business, and our private label and bulk nutritional supplements business in particular, rely on operational efficiency to mass produce products at low margins per unit. We also rely on numerous third parties to supply production materials and in some cases there may not be alternative sources immediately available.

In addition, we currently rely on nine significant third-party manufacturers, as well as numerous other less significant manufacturers, to produce many of our professional diagnostic products and certain components of our consumer diagnostic products, including products in development. In addition, certain of the products acquired as part of the Abbott rapid diagnostics business are currently manufactured for us by Abbott Laboratories in Chicago under the terms of a transitional arrangement. Any event impacting our manufacturing facilities, our manufacturing systems or equipment, or our contract manufacturers or suppliers, including, without limitation, wars, terrorist activities, natural disasters and outbreaks of infectious disease, could delay or suspend shipments of products or the release of new products or could result in the delivery of inferior products. Our revenues from the affected products would decline or we could incur losses until such time as we were able to restore our production processes or put in place alternative contract manufacturers or suppliers. Even though we carry business interruption insurance policies, we may suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies.

We may experience difficulties that may delay or prevent our development, introduction or marketing of new or enhanced products.

We intend to continue to invest in product and technology development. The development of new or enhanced products is a complex and uncertain process. We may experience research and development, manufacturing, marketing and other difficulties that could delay or prevent our development, introduction or marketing of new products or enhancements. We cannot be certain that:

any of the products under development will prove to be effective in clinical trials;

we will be able to obtain, in a timely manner or at all, regulatory approval to market any of our products that are in development or contemplated;

any of such products can be manufactured at acceptable cost and with appropriate quality; or

any such products, if and when approved, can be successfully marketed.

The factors listed above, as well as manufacturing or distribution problems, or other factors beyond our control, could delay new product launches. In addition, we cannot assure you that the market will accept these products. Accordingly, there is no assurance that our overall revenues will increase if and when new products are launched.

We may experience difficulties that may delay or prevent us from completing our plans to centralize our U.S. consumer products packaging and distribution facilities, and our plans to manufacture certain products in China.

We have commenced operations of our centralized U.S. packaging and distribution facility serving our consumer diagnostic and vitamins and nutritional supplements segments and begun to transition the manufacture of certain products to China. We may not complete our plans with respect to these operations in the time projected, or at all, if we are unable to develop or finalize the necessary third party relationships; acquire the required facilities, equipment or materials; or obtain any necessary consents or approvals. In addition, even if we do succeed in developing these new operations on schedule, operational problems, or other factors beyond our control, may prevent or delay us from recognizing cost savings, margin improvements or other benefits that we may expect.

Our failure to meet strict regulatory requirements, could require us to pay fines, incur other cost or even close our facilities.

Our facilities and manufacturing techniques generally must conform to standards that are established by government agencies, including those of European and other foreign governments, as well as the FDA, and, to a lesser extent, the U.S. Drug Enforcement Administration, or the DEA, and local health agencies. These regulatory agencies may conduct periodic audits of our facilities or our processes to monitor our compliance with applicable regulatory standards. If a regulatory agency finds that we fail to comply with the appropriate regulatory standards, it may impose fines on us, delay or withdraw pre-market clearances or other regulatory approvals or if such a regulatory agency determines that our non-compliance is severe, it may close our facilities. Any adverse action by an applicable regulatory agency could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers demands. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and profits.

In March 2005, our ABI subsidiary was informed by the FDA that based on inspectional findings that included data integrity and design control issues, ABI has become subject to the FDA s Application Integrity Policy. As a result, the FDA will defer the review of any pending or future applications made by ABI until the FDA determines that ABI has resolved these issues. ABI currently has no applications pending. At this time ABI is not restricted with regard to introducing new tests outside of the United States, or from selling products in the United States based on any existing 510(k)s. However, ABI has decided to withdraw certain 510(k)s related to its drugs of abuse products that were cited by the FDA, and a Class III recall (based on our assessment that any hazard to the public health is unlikely) will be issued for the corresponding products. ABI is undertaking both an internal and external audit, and is committed to taking any actions required by those audits in order to fulfill its regulatory obligations. It is our understanding at this time that the FDA action applies only to ABI and does not otherwise restrict our ability, or the ability of our other subsidiaries, to submit applications to the FDA or commercialize products. However, the scope of the FDA action is uncertain, and may have a negative impact on our future sales and profits.

Regulatory agencies may also impose new or enhanced standards that would increase our costs as well as the risks associated with non-compliance. For example, we anticipate that the FDA may soon finalize and implement good manufacturing practice, or GMP, regulations for nutritional supplements. GMP regulations would require supplements to be prepared, packaged and held in compliance with certain rules,

and might require quality control provisions similar to those in the GMP regulations for drugs. While our manufacturing facilities for nutritional supplements have been subjected to, and passed, third party inspections against anticipated GMP standards, the ongoing compliance required in the event that GMP regulations are adopted would involve additional costs and would present new risks associated with any failure to comply with the regulations in the future.

If we deliver products with defects, our credibility may be harmed, market acceptance of our products may decrease and we may be exposed to liability in excess of our product liability insurance coverage.

The manufacturing and marketing of consumer and professional diagnostic products involve an inherent risk of product liability claims. In addition, our product development and production are extremely complex and could expose our products to defects. Any defects could harm our credibility and decrease market acceptance of our products. In addition, our marketing of vitamins and nutritional supplements may cause us to be subjected to various product liability claims, including, among others, claims that the vitamins and nutritional supplements have inadequate warnings concerning side effects and interactions with other substances. Potential product liability claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of the policy. In the event that we are held liable for a claim for which we are not indemnified, or for damages exceeding the limits of our insurance coverage, that claim could materially damage our business and our financial condition.

Our sales of branded nutritional supplements have been trending downward since 1998 due to the maturity of the market segments they serve and the age of that product line and we may experience further declines in sales of those products.

Our aggregate sales of all of our brand name nutritional products, including, among others, Ferro-Sequels, Stresstabs, Protegra, Posture, SoyCare, ALLBEE, and Z-BEC, have declined each year since 1998 through the year 2004, except in 2002 when they increased slightly as compared to 2001. We believe that these products have under-performed because they are, for the most part, aging brands with limited brand recognition that face increasing private label competition. The overall age of this product line means that we are subject to future distribution loss for under-performing brands, while our opportunities for new distribution on the existing product lines are limited. As a result we do not expect significant sales growth of our existing brand name nutritional products and we may experience further declines in overall sales of our brand name nutritional products in the future.

Our sales of specific vitamins and nutritional supplements could be negatively impacted by media attention or other news developments that challenge the safety and effectiveness of those specific vitamins and nutritional supplements.

Most growth in the vitamin and nutritional supplement industry is attributed to new products that tend to generate greater attention in the marketplace than do older products. Positive media attention resulting from new scientific studies or announcements can spur rapid growth in individual segments of the market, and also impact individual brands. Conversely, news that challenges individual segments or products can have a negative impact on the industry overall as well as on sales of the challenged segments or products. Most of our vitamin and nutritional supplements products serve well-established market segments and, absent unforeseen new developments or trends, are not expected to benefit from rapid growth. A few of our vitamin and nutritional products are newer products that are more likely to be the subject of new scientific studies or announcements, which could be either positive or negative. News or other developments that challenge the safety or effectiveness of these products could negatively impact the profitability of our vitamin and nutritional supplements business. Recent negative press regarding the effects of high doses of Vitamin E based on certain studies, the conclusions of which are open to interpretation and challenge, has negatively impacted our sales of Vitamin E products, and could continue to negatively impact this business segment unless these studies are publicly challenged or refuted.

We could suffer monetary damages, incur substantial costs or be prevented from using technologies important to our products as a result of a number of pending legal proceedings.

We are involved in various legal proceedings arising out of our consumer diagnostics, nutritional supplements and professional diagnostics business. Because of the nature of our business, we may be subject at any particular time to commercial disputes, consumer product claims or various other lawsuits arising in the ordinary course of our business, including employment matters, and expect that this will continue to be the case in the future. Such 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. An adverse ruling or rulings in one or more such lawsuits could, individually or in the aggregate, have a material adverse effect on our sales, operations or financial performance. In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties, such as our litigation against Acon Laboratories. These suits can be expensive and result in counterclaims challenging the validity of our patents and other rights. We cannot assure you that these lawsuits or any future lawsuits relating to our businesses will not have a material adverse effect on us.

The profitability of our consumer products businesses may suffer if we are unable to establish and maintain close working relationships with our customers.

For the years ended December 31, 2004 and 2003, approximately two-thirds of our net product sales, respectively, were derived from our consumer products business, which consists of our consumer diagnostic products and vitamin and nutritional supplements segments. These businesses rely to a great extent on close working relationships with our customers rather than long-term exclusive contractual arrangements. Customer concentration in these businesses is relatively high, especially in our vitamin and nutritional supplements segment where two customers currently account for almost 65% of sales. In addition, customers of our branded and private label consumer products businesses purchase products through purchase orders only and are not obligated to make future purchases. We therefore rely on our ability to deliver quality products on time in order to retain and generate customers. If we fail to meet our customers needs or expectations, whether due to manufacturing issues that affect quality or capacity issues that result in late shipments, we will harm our reputation and customer relationships and likely lose customers. Additionally, if we are unable to maintain close working relationships with our customers, sales of all of our products and our ability to successfully launch new products could suffer. The loss of a major customer and the failure to generate new accounts could significantly reduce our revenues or prevent us from achieving projected growth.

The profitability of our consumer products businesses may suffer if Pfizer Inc. is unable to successfully market and sell its e.p.t pregnancy tests.

Under the terms of a manufacturing, packaging and supply agreement that we entered into with Pfizer Inc., through one of its wholly-owned subsidiaries, Pfizer will purchase its non-digital e.p.t pregnancy tests from us beginning on June 6, 2004 and continuing until June 6, 2009. Additionally, under the terms of a separate supply agreement, in December 2003, we began supplying Pfizer with a digital version of its e.p.t pregnancy test on a non-exclusive basis. The amount of revenues or profits that we generate under these agreements will depend on the volume of orders that we receive from Pfizer. As a result, if Pfizer is unable to successfully market and sell its e.p.t pregnancy tests, or if other events adversely affect the volume of Pfizer s sales of its e.p.t pregnancy tests, then our future revenues and profit may be adversely affected.

Because sales of our private label nutritional supplements are generally made at low margins, the profitability of these products may suffer significantly as a result of relatively small increases in raw material or other manufacturing costs.

Sales of our private label nutritional supplements, which for the years ended December 31, 2004 and 2003, provided approximately 17% and 20%, respectively, of our net product sales, generate low profit margins. We rely on our ability to efficiently mass produce nutritional supplements in order to make meaningful profits from these products. Changes in raw material or other manufacturing costs can drastically cut into or eliminate the profits generated from the sale of a particular product. For the most part, we do not have long-term supply contracts for our required raw materials and, as a result, our costs can increase with little notice. The private label nutritional supplements business is also highly competitive such that our ability to raise prices as a result of increased costs is limited. Customers generally purchase private label products via purchase order, not through long-term contracts, and they often purchase these products from the lowest bidder on a product by product basis. The internet has enhanced price competition among private label manufacturers through the advent of on-line auctions, where customers will auction off the right to manufacture a particular product to the lowest bidder. The resulting margin erosion in our nutritionals business has resulted in a reduction in our overall gross margin and contributed to our losses in 2004, as compared to our income in 2003.

Our financial condition or results of operations may be adversely affected by international business risks.

Approximately 40% and 36% of our net revenues were generated from outside the United States for the year ended December 31, 2004 and 2003, respectively. A significant number of our employees, including manufacturing, sales, support and research and development personnel, are located in foreign countries, including England, Ireland and Israel. Conducting business outside of the United States subjects us to numerous risks, including:

increased costs or reduced revenue as a result of movements in foreign currency exchange rates;

decreased liquidity resulting from longer accounts receivable collection cycles typical of foreign countries;

lower productivity resulting from difficulties managing our sales, support and research and development operations across many countries;

lost revenues resulting from difficulties associated with enforcing agreements and collecting receivables through foreign legal systems;

lost revenues resulting from the imposition by foreign governments of trade protection measures;

higher cost of sales resulting from import or export licensing requirements;

lost revenues or other adverse affects as a result of economic or political instability in or affecting foreign countries in which we sell our products or operate; and

adverse effects resulting from changes in foreign regulatory or other laws affecting the sales of our products or our foreign operations.

Because our business relies heavily on foreign operations and revenues, changes in foreign currency exchange rates and our ability to convert currencies may negatively affect our financial condition and results of operations.

Our business relies heavily on our foreign operations. Four of our manufacturing facilities are outside the United States, in Bedford, England, Galway, Ireland, Shanghai, China and Yavne, Israel. We have also announced plans to consolidate much of our cardiovascular related research and development in Scotland and ultimately to establish a significant manufacturing operation there. Approximately 40% and 36% of our net revenues were generated from outside the United States for the year ended December 31, 2004 and 2003, respectively. Our Clearblue pregnancy test product sales have historically been much stronger outside the United States, with 74% of net product sales of these products coming from outside the United States during the year ended December 31,

2004. In addition, the Abbott rapid diagnostics business, which we acquired on September 30, 2003, generates a majority of its sales outside the United States. Because of our foreign operations and foreign sales, we face exposure to movements in foreign currency exchange rates. Our primary exposures are related to the operations of our European subsidiaries. These exposures may change over time as business practices evolve and could result in increased costs or reduced revenue and could impact our actual cash flow.

Intense competition could reduce our market share or limit our ability to increase market share, which could impair the sales of our products and harm our financial performance.

The medical products industry is rapidly evolving and developments are expected to continue at a rapid pace. Competition in this industry, which includes both our consumer diagnostics and professional diagnostics businesses, is intense and expected to increase as new products and technologies become available and new competitors enter the market. Our competitors in the United States and abroad are numerous and include, among others, diagnostic testing and medical products companies, universities and other research institutions. Our future success depends upon maintaining a competitive position in the development of products and technologies in our areas of focus. Our competitors may:

develop technologies and products that are more effective than our products or that render our technologies or products obsolete or noncompetitive;

obtain patent protection or other intellectual property rights that would prevent us from developing our potential products; or

obtain regulatory approval for the commercialization of their products more rapidly or effectively than we do.

Also, the possibility of patent disputes with competitors holding foreign patent rights may limit or delay expansion possibilities for our diagnostics businesses in certain foreign jurisdictions. In addition, many of our existing or potential competitors have or may have substantially greater research and development capabilities, clinical, manufacturing, regulatory and marketing experience and financial and managerial resources.

The market for the sale of vitamins and nutritional supplements is also highly competitive. This competition is based principally upon price, quality of products, customer service and marketing support. There are numerous companies in the vitamins and nutritional supplements industry selling products to retailers such as mass merchandisers, drug store chains, independent drug stores, supermarkets, groceries and health food stores. As most of these companies are privately held, we are unable to obtain the information necessary to assess precisely the size and success of these competitors. However, we believe that a number of our competitors, particularly manufacturers of nationally advertised brand name products, are substantially larger than we are and have greater financial resources.

The rights we rely upon to protect the intellectual property underlying our products may not be adequate, which could enable third parties to use our technology and would reduce our ability to compete in the market.

Our success will depend in part on our ability to develop or acquire commercially valuable patent rights and to protect our intellectual property. Our patent position is generally uncertain and involves complex legal and factual questions. The degree of present and future protection for our proprietary rights is uncertain.

The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

the pending patent applications we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents;

the claims of any patents which are issued may not provide meaningful protection;

we may not be able to develop additional proprietary technologies that are patentable;

the patents licensed or issued to us or our customers may not provide a competitive advantage;

other parties may challenge patents or patent applications licensed or issued to us or our customers;

patents issued to other companies may harm our ability to do business; and

other companies may design around technologies we have patented, licensed or developed.

In addition to patents, we rely on a combination of trade secrets, nondisclosure agreements and other contractual provisions and technical measures to protect our intellectual property rights. Nevertheless, these measures may not be adequate to safeguard the technology underlying our products. If they do not protect our rights, third parties could use our technology and our ability to compete in the market would be reduced. In addition, employees, consultants and others who participate in the development of our products may breach their agreements with us regarding our intellectual property and we may not have adequate remedies for the breach. We also may not be able to effectively protect our intellectual property rights in some foreign countries. For a variety of reasons, we may decide not to file for patent, copyright or trademark protection or prosecute potential infringements of our patents. We also realize that our trade secrets may become known through other means not currently foreseen by us. Despite our efforts to protect our intellectual property, our competitors or customers may independently develop similar or alternative technologies or products that are equal or superior to our technology and products without infringing on any of our intellectual property rights or design around our proprietary technologies.

Claims by other companies that our products infringe on their proprietary rights could adversely affect our ability to sell our products and increase our costs.

Substantial litigation over intellectual property rights exists in both the consumer and professional diagnostic industries. We expect that our products and products in these industries could be increasingly subject to third party infringement claims as the number of competitors grows and the functionality of products and technology in different industry segments overlaps. Third parties may currently have, or may eventually be issued, patents on which our products or technology may infringe. Any of these third parties might make a claim of infringement against us. Any litigation could result in the expenditure of significant financial resources and the diversion of management s time and resources. In addition, litigation in which we are accused of infringement may cause negative publicity, have an impact on prospective customers, cause product shipment delays or require us to develop non-infringing technology, make substantial payments to third parties, or enter into royalty or license agreements, which may not be available on acceptable terms, or at all. If a successful claim of infringement was made against us and we could not develop non-infringing technology or license the infringed or similar technology on a timely and cost-effective basis, our revenue may decrease and we could be exposed to legal actions by our customers.

We have initiated, and may need to further initiate, lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would reduce our ability to compete in the market.

We rely on patents to protect a portion of our intellectual property and our competitive position. In order to protect or enforce our patent rights, we may initiate patent litigation against third parties, such as infringement suits or interference proceedings. Litigation may be necessary to:

assert claims of infringement;

enforce our patents;

protect our trade secrets or know-how; or

determine the enforceability, scope and validity of the proprietary rights of others.

Currently, we have initiated a number of lawsuits against competitors who we believe to be selling products that infringe our proprietary rights. These current lawsuits and any other lawsuits that we initiate could be expensive, take significant time and divert management s attention from other business concerns. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third parties to assert claims against us.

Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in our industry are generally uncertain. We may not prevail in any of these suits and the damages or other remedies awarded, if any, may not be commercially valuable. During the course of these suits, there may be public announcements of the results of hearings, motions and other interim proceedings or developments in the litigation. If securities analysts or investors perceive any of these results to be negative, our stock price could decline.

Non-competition obligations and other restrictions will limit our ability to take full advantage of our management team, the technology we own or license and our research and development capabilities.

Members of our management team have had significant experience in the diabetes field. In addition, technology we own or license may have potential applications to this field and our research and development capabilities could be applied to this field. However, in conjunction with our split-off from Inverness Medical Technology, Inc., or IMT, we agreed not to compete with IMT and

Johnson & Johnson in the field of diabetes through 2011. In addition, Mr. Ron Zwanziger, our Chairman, Chief Executive Officer and President, and two of our senior scientists, Dr. David Scott and Dr. Jerry McAleer, have entered into consulting agreements with IMT that impose similar restrictions. Further, our license agreement with IMT prevents us from using any of the licensed technology in the field of diabetes. As a result of these restrictions, we cannot pursue opportunities in the field of diabetes.

You are unlikely to be able to exercise effective remedies against Arthur Andersen LLP, our former independent public accountants.

Although we dismissed Arthur Andersen LLP as our independent public accountants in June 2002 and we now engage BDO Seidman, LLP, independent registered public accounting firm, our consolidated financial statements as of December 31, 2001 and 2000, to the extent included in this report or in previously filed reports or registrations statements were audited by Arthur Andersen.

On March 14, 2002, Arthur Andersen was indicted on federal obstruction of justice charges arising from the government s investigation of Enron Corporation. On June 15, 2002, a jury in Houston, Texas found Arthur Andersen guilty of these federal obstruction of justice charges. In light of the jury verdict and the underlying events, Arthur Andersen subsequently substantially discontinued operations and dismissed essentially its entire workforce. You are therefore unlikely to be able to exercise effective remedies or collect judgments against Arthur Andersen for any untrue statement of a material fact contained in the financial statements audited by Arthur Andersen or any omissions to state a material fact required to be stated in those financial statements.

Our operating results may fluctuate due to various factors and as a result period-to-period comparisons of our results of operations will not necessarily be meaningful.

Factors relating to our business make our future operating results uncertain and may cause them to fluctuate from period to period. Such factors include:

- the timing of new product announcements and introductions by us and our competitors;
- market acceptance of new or enhanced versions of our products;
- changes in manufacturing costs or other expenses;
- competitive pricing pressures;
- the gain or loss of significant distribution outlets or customers;

increased research and development expenses;

the timing of any future acquisitions;

general economic conditions; or

general stock market conditions or other economic or external factors.

Because our operating results may fluctuate from quarter to quarter, it may be difficult for us or our investors to predict our future performance by viewing our historical operating results.

Period-to-period comparisons of our operating results may not be meaningful due to our acquisitions.

We have engaged in a number of significant acquisitions in recent years which make it difficult to analyze our results and to compare them from period to period, including the acquisitions of the Unipath business in December 2001, IVC Industies, Inc. in March 2002, Wampole in September 2002, Ostex in June 2003, ABI in August 2003, the Abbott rapid diagnostics product lines in September 2003, and Binax and Ischemia in March 2005. Period-to-period comparisons of our results of operations may not be meaningful due to these acquisitions and are not indications of our future performance. Any future acquisitions will also make our results difficult to compare from period to period in the future.

Our stock price may fluctuate significantly and stockholders who buy or sell our common stock may lose all or part of the value of their investment, depending on the price of our common stock from time to time.

Our common stock has only been listed on the American Stock Exchange since November 23, 2001 and we have a limited market capitalization. As a result, we are currently followed by only a few market analysts and a portion of the investment community. Limited trading of our common stock may therefore make it more difficult for you to sell your shares.

In addition, our share price may be volatile due to our operating results, as well as factors beyond our control. During 2004, the sales price of our common stock ranged from $14.75 to $25.50, and during 2003, the sales price of our common stock ranged from $13.40 to $27.50. It is possible that in some future periods the results of our operations will be below the expectations of the public market. In any such event, the market price of our common stock could decline. Furthermore, the stock market may experience significant price and volume fluctuations, which may affect the market price of our common stock for reasons unrelated to our operating performance. The market price of our common stock may be highly volatile and may be affected by factors such as:

our quarterly and annual operating results, including our failure to meet the performance estimates of securities analysts;

changes in financial estimates of our revenues and operating results or buy/sell recommendations by securities analysts;

the timing of announcements by us or our competitors of significant products, contracts or acquisitions or publicity regarding actual or potential results or performance thereof;

changes in general conditions in the economy, the financial markets or the health care industry;

government regulation in the health care industry;

changes in other areas such as tax laws;

sales of substantial amounts of common stock or the perception that such sales could occur;

changes in investor perception of our industry, our businesses or our prospects;

the loss of key employees, officers or directors; or

other developments affecting us or our competitors.

Anti-takeover provisions in our organizational documents and Delaware law may limit the ability of our stockholders to control our policies and effect a change of control of our company and prevent attempts by our stockholders to replace or remove our current management, which may not be in your best interests.

There are provisions in our certificate of incorporation and bylaws that may discourage a third party from making a proposal to acquire us, even if some of our stockholders might consider the proposal to be in their best interests, and prevent attempts by our stockholders to replace or remove our current management. These provisions include the following:

our certificate of incorporation provides for three classes of directors with the term of office of one class expiring each year, commonly referred to as a staggered board. By preventing stockholders from voting on the election of more than one class of directors at any annual meeting of stockholders, this provision may have the effect of keeping the current members of our board of directors in control for a longer period of time than stockholders may desire;

our certificate of incorporation authorizes our board of directors to issue shares of preferred stock without stockholder approval and to establish the preferences and rights of any preferred stock issued, which would allow the board to issue one or more classes or series of preferred stock that could discourage or delay a tender offer or change in control.

our certificate of incorporation prohibits our stockholders from filling board vacancies, calling special stockholder meetings or taking action by written consent;

our certificate of incorporation provides for the removal of a director only with cause and by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of our directors; and

our bylaws require advance written notice of stockholder proposals and director nominations.

Additionally, we are subject to Section 203 of the Delaware General Corporation Law, which, in general, imposes restrictions upon acquirers of 15% or more of our stock. Finally, the board of directors may in the future adopt other protective measures, such as a stockholder rights plan, which could delay, deter or prevent a change of control.

Because we do not intend to pay dividends on our common stock, you will benefit from an investment in our common stock only if it appreciates in value.

We currently intend to retain our future earnings, if any, to finance the expansion of our business and do not expect to pay any cash dividends on our common stock in the foreseeable future. In addition, our senior credit facility currently prohibits the payment of dividends and the indenture governing the terms of our senior subordinated notes restricts the amount of any dividends that we may pay. As a result, the success of your investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value or even maintain the price at which you purchased your shares.

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 w 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 the Certain Factors Affecting Future Results section in this report and other risk factors identified from time to time in our periodic filings with the SEC. Some important additional 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;

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

the impact of business combinations, including acquisitions and divestitures, such as our acquisitions of Applied Biotech, Inc. and the Abbott rapid diagnostics product lines, and organizational restructurings consistent with evolving business strategies;

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 March 31, 2005, our short-term investments approximated market value.

At March 31, 2005, we had revolving lines of credit available to us of up to $50.0 million in the aggregate under our primary senior credit facility, against which $8.0 million was outstanding. 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, 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 March 31, 2005, the LIBOR and Index rates applicable under our primary senior credit facility were 2.87% and 5.75%, 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 March 31, 2005 over the next twelve months is quantified and summarized as follows:

(in thousands)	Interest Expense Increase
Interest rates increase by 1 basis point	$ 420
Interest rates increase by 2 basis points	840

Foreign Currency Risk

We face exposure to movements in foreign currency exchange rates whenever we, or any of our subsidiaries, enter into transactions with third parties that are denominated in currencies other than our, or its, functional currency. Intercompany transactions between entities that use different functional currencies also expose us to foreign currency risk. During the three months ended March 31, 2005, the net impact of foreign currency changes on transactions was a gain of $0.2 million. Generally, we do not use derivative financial instruments or other financial instruments with original maturities in excess of three months to hedge such economic exposures. However, due to the continued decline in value of the U.S. Dollar and our continued foreign currency exchange exposure in transactions involving the U.S. Dollar, we have entered into forward currency exchange contracts with maturities in excess of three months, but within one year, starting in the first quarter of 2005.

Gross margins of products we manufacture at our European plants and sell in U.S. Dollar are also affected by foreign currency exchange rate movements. Our gross margin on total net product sales was 34.5% for the three months ended March 31, 2005. If the U.S. Dollar had been stronger by 1%, 5% or 10%, compared to the actual rates during the three months ended March 31, 2005, our gross margin on total net product sales would have been 34.7%, 35.2% and 35.9%, 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)

If during the three months ended March 31, 2005, the U.S. dollar was stronger by:	**Approximate decrease in net revenue**	**Approximate decrease in net loss**
1%	$ 312	$ 2
5%	1,561	10
10%	3,121	20

ITEM 4. CONTROLS AND PROCEDURES

On June 28, 2005, we announced that certain of our previously issued financial statements must be restated because they contain errors under GAAP relating to the recognition of revenue at one of our diagnostic divisions. We determined that certain customers of this division were provided previously unidentified return or exchange rights in connection with the sale of certain products for which reliable estimates of return or exchange had not been made, as a result of which the revenue associated with those sales should not have been recognized upon shipment to the customers under GAAP. As a result, we determined that we needed to restate our financial statements for the fiscal years ended December 31, 2004 and December 31, 2003, for each of the quarters in fiscal 2004 and 2003 and for this quarter ended March 31, 2005. For a more detailed discussion regarding the restatements, see Note 2 to our consolidated financial statements included herein.

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. As part of its evaluation management considered the facts and circumstances relating to the restatement discussed above and determined that there existed at the affected diagnostic division material weaknesses in internal control over financial reporting. The material weaknesses resulted from weaknesses in the design of controls established to ensure that any modifications to material financial terms and conditions of sales contracts come to the attention of management responsible for financial reporting in a timely manner and were properly accounted for. Based on this evaluation, our management, including the CEO and CFO, concluded that our company s disclosure controls and procedures were not operating effectively as of March 31, 2005 due to the material weaknesses which resulted in the restatement of our previously issued financial statements as discussed above.

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. However, in connection with the restatements discussed above, special counsel to the Audit Committee of our Board of Directors has made certain recommendations to the Audit Committee regarding proposed enhancements to the design of our internal controls. The Audit Committee and management have approved these proposals and we intend to make changes to our internal control over financial reporting in the near future in order to remediate the material weakness discussed above.

PART II - OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Inverness Medical Switzerland GmbH, et al. v. Princeton Biomeditech Corporation

We previously had several lawsuits pending against Pfizer Inc. and certain other parties, including Princeton BioMeditech, or PBM, in the United States District Court for the District of New Jersey alleging, among other things, that pregnancy tests manufactured or sold by the defendants infringe patents owned by us. In early June 2003, we settled our litigation against Pfizer. However, our claims against PBM, who had brought several counterclaims against us, had remained active. PBM s counterclaims alleged, among other things, that we have breached various obligations to PBM arising out of a joint venture with us.

On April 6, 2005, we entered into a binding settlement agreement of our pending litigation with PBM pursuant to which we paid $2.5 million in resolution of all pending litigation with PBM, which will be dismissed without prejudice, but with both parties agreeing to certain limits on their ability to recommence litigation. PBM also receives an option to permanently settle with prejudice certain claims against ABI that are not part of any pending case in exchange for $1.75 million of collaborative research and development funding from us. The parties also exchanged limited, non-transferable covenants not to sue the other for infringement of existing intellectual property and the parties have agreed to certain other terms and conditions relating to the use and enforcement of intellectual property owned by a previously existing joint venture between them. In connection with the settlement the parties also entered into an agreement to form a joint venture pursuant to which both companies will make all their sales of existing drugs of abuse products (excluding sales to hospitals) (the New Joint Venture). All products sold by the New Joint Venture will be manufactured by PBM. The New Joint Venture will be owned equally by PBM and us and profits will be distributed in proportion to the trailing 12 month sales of products contributed to the venture.

Quidel Corporation v. Inverness Medical Innovations, Inc., et al.

In January 2004, our subsidiary, Inverness Medical Switzerland, GmbH (IMS), filed suit against Quidel Corporation in Germany seeking damages and injunction for infringement of certain of our patents. In response, on February 20, 2004, Quidel named us and our subsidiaries IMS and ABI as defendants in a suit filed in the United States District Court for the Southern District of California. Quidel alleged that we were infringing U.S. Patent No. 4,943,522. Quidel also asked the Court for a declaratory finding that Quidel does not infringe certain patents owned by IMS and certain other patents owned by co-defendant Armkel LLC to which we have a license, and that these patents are invalid and/or unenforceable. Quidel sought injunctive relief and damages. In early March 2004, we filed an answer claiming that Quidel s claims were without merit and a counterclaim seeking damages and injunctive relief for Quidel s infringement of these patents. We also filed a separate action against Quidel in the same court alleging infringement of certain other patents and seeking injunctive relief and damages. In September 2004, Quidel served a suit on Unipath Diagnostics GmbH and its directors in the District Court of Mannheim, Germany, alleging infringement of the German equivalent of the Quidel patent. We responded, denying liability

On April 27, 2005 we entered into a settlement agreement with Quidel Corporation terminating all domestic and international intellectual property litigation with them. Under the settlement agreement, we will receive a net payment of $17 million and net future royalties from Quidel at 8.5%, in exchange for a license to all of our current and future patents which embody lateral flow technology for all diagnostic products other than for cardiology testing and for consumer/over-the-counter women s health (except that diagnostics for women s infectious diseases are within the licensed field of use). Quidel and its affiliates are granting a net royalty free cross-license of their current and future patents that embody lateral flow technology to us and all of our affiliates for all applications.

Other Pending and Potential Litigation and Proceedings

Because of the nature of our business, we may be subject at any particular time to consumer product claims or various other lawsuits arising in the ordinary course of our business, including employment matters, and expect that this will continue to be the case in the future. Such lawsuits generally seek damages, sometimes in substantial amounts, for personal injuries or other commercial or employment claims. In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties. We have approximately 13 lawsuits pending around the world against competitors whom we believe to be selling products that infringe our propriety rights, including our ongoing litigation against Acon Laboratories. These suits can be expensive and result in counterclaims challenging the validity of our patents and other rights.

ITEM 6. **EXHIBITS**

Exhibits:

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated February 8, 2005, by and among Inverness Medical Innovations, Inc., a Delaware corporation to be formed as a wholly-owned subsidiary of Inverness Medical Innovations, Inc., Binax, Inc., Roger N. Piasio and Myron C. Hamer, and Roger N. Piasio, as stockholder representative (incorporated by reference to Exhibit 99.1 to the Company s Current Report of Form 8-K dated February 9, 2005)
2.2	Agreement and Plan of Merger, dated February 15, 2005, by and among Inverness Medical Innovations, Inc., a Delaware corporation to be formed as a wholly-owned subsidiary of Inverness Medical Innovations, Inc., and Ischemia Technologies, Inc. (incorporated by reference to Exhibit 99.1 to the Company s current report on form 8-K dated February 15, 2005)
*4.1	Third Supplement Indenture, dated as of March 16, 2005, among Inverness Medical Innovations, Inc., the Guarantors, Ischemia Technologies, Inc. and U.S. Bank Trust National Association, as Trustee.
*4.2	Fourth Supplement Indenture, dated as of March 31, 2005, among Inverness Medical Innovations, Inc., the Guarantors, Binax, Inc. and U.S. Bank Trust National Association, as Trustee.
*10.1	Twelfth Amendment and Consent to Second Amended and Restated Credit Agreement, dated as of February 23, 2005 by and among
*+10.2	Research and Development Agreement, dated February 25, 2005, among ITI Scotland Limited and Inverness Medical Innovations, Inc., Stirling Medical Innovations Limited and Inverness Medical Switzerland GmbH
**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

* previously filed

** filed herewith

+ portions of this exhibit have been omitted pursuant to a request for confidential treatment

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INVERNESS MEDICAL INNOVATIONS, INC.

Date: August 26, 2005

/s/ Christopher J. Lindop
Christopher J. Lindop
Chief Financial Officer and an authorized officer