INVERNESS MEDICAL INNOVATIONS INC
Form 10-Q/A
February 14, 2005

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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 September 30, 2004

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

The number of shares outstanding of the registrant's common stock as of November 5, 2004 was 20,340,122.

INVERNESS MEDICAL INNOVATIONS, INC.
FORM 10-Q
For the Quarterly Period Ended September 30, 2004

This quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Readers can identify these statements by forward-looking words such as "may," "could," "should," "would," "intend," "will," "expect," "anticipate," "believe," "estimate," "continue" or similar words. There are a number of important factors that could cause actual results of Inverness Medical Innovations, Inc. and its subsidiaries to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the risk factors detailed in 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 45 and 61, 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.

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

We have registered or are using the following trademarks which appear in this quarterly report on Form 10-Q: Clearblue , Clearblue Easy®, Fact plus®, Persona®, Clearview®, Wampole®, Testpack , Signify®, Ferro-Sequels , Stresstabs®, Protegra®, Posture®, SoyCare , ALLBEE®, and Z-BEC®.

The following are registered trademarks of parties other than us: Abbott®, Abbott TestPack®, Abbott TestPack plus® and e.p.t®.

TABLE OF CONTENTS

EXPLANATORY NOTE

On December 2, 2004, we announced that our previously issued consolidated financial statements as of and for the years ended December 31, 2002 and 2003, and for the interim periods during 2004, contained an error in the application of accounting principles generally accepted in the United States of America relating to the calculation of our provision for income taxes and the related deferred taxes. In connection with a routine review of our Annual Report on Form 10-K for the fiscal year ended December 31, 2003, as amended ("Form 10-K"), by the Securities and Exchange Commission's Division of Corporation Finance, we also revised our purchase price allocation in connection with our acquisition of the rapid diagnostics business that we acquired from Abbott Laboratories on September 30, 2003 in order to attribute approximately $5.7 million to customer related intangible assets acquired in the acquisition and to reduce goodwill by the same amount. We have also recorded as of the date of the acquisition approximately $11.3 million in other assets acquired from Abbott Laboratories, the amortization of which amounted to approximately $50,000 per quarter, that we had originally recognized in our Quarterly Report on Form 10-Q for the period ended September 30, 2004 (the "Original Report"), and commenced amortization in connection with all amortizable acquired assets as of the same date. The impact of all additional non-cash amortization on our operating results, net of tax effect, was to reduce previously reported net income by approximately $800,000, or $0.04 per share, for the third quarter of 2004. This Amendment No. 1 (the "Amended Report") to Original Report has been filed to address both these issues in the Original Report and in the consolidated financial statements as of September 30, 2004 and for the three and nine months ended September 30, 2004 and 2003, respectively, contained therein. We have also amended our Form 10-K and our Quarterly Reports on Form 10-Q for the periods ended March 31, 2004 and June 30, 2004.

The correction of the error relating to our tax provision results in an incremental non-cash provision of income taxes. The changes to our purchase price allocation for the acquisition of the rapid diagnostics business from Abbott Laboratories result in additional non-cash amortization over the lives of the assets identified.

For the reasons discussed above, we are filing this Amended Report in order to amend Part I. Item 1 "Consolidated Financial Statements (unaudited)," Part I. Item 2 "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Part II. Item 6 "Exhibits and Reports on Form 8-K" of the Original Report to the extent necessary to reflect the adjustments discussed above. 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, November 9, 2004, 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 September 30,		Nine Months Ended September 30,	
	2004	**2003**	**2004**	**2003**
	(restated)	**(restated)**	**(restated)**	**(restated)**
Net product sales	$ 94,698	$ 69,278	$ 269,629	$ 196,182
License revenue	2,807	3,115	7,304	7,030
Net revenue	97,505	72,393	276,933	203,212
Cost of sales (Note 11)	59,171	40,902	166,686	113,217
Gross profit	38,334	31,491	110,247	89,995
Operating expenses:				
Research and development	7,850	6,413	23,265	17,055
Sales and marketing	14,824	13,251	42,836	36,949
General and administrative	13,053	7,637	38,510	24,013
Stock-based compensation(1)		60		66
Total operating expenses	35,727	27,361	104,611	78,083
Operating income	2,607	4,130	5,636	11,912
Interest expense, including amortization of discounts and write-off of deferred financing costs (Note 8)	(4,846)	(2,443)	(17,157)	(6,723)
Other income, net	1,179	367	1,655	6,387
(Loss) income before income taxes	(1,060)	2,054	(9,866)	11,576
Income tax provision	1,202	773	3,124	3,162
Net (loss) income	$ (2,262)	$ 1,281	$ (12,990)	$ 8,414
Net (loss) income available to common stockholders basic (Note 5)	$ (2,262)	$ 1,138	$ (13,739)	$ 7,956
Net (loss) income available to common stockholders diluted (Note 5)	$ (2,262)	$ 1,138	$ (13,739)	$ 8,091
Net (loss) income per common share basic (Note 5)	$ (0.11)	$ 0.07	$ (0.69)	$ 0.54

	Three Months Ended September 30,		Nine Months Ended September 30,	
Net (loss) income per common share diluted (Note 5)	$ (0.11)	$ 0.06	$ (0.69)	$ 0.48
Weighted average shares basic (Note 5)	20,296	16,301	19,813	14,719
Weighted average shares diluted (Note 5)	20,296	18,176	19,813	16,788

(1) The charge for stock-based compensation for the three and nine months ended September 30, 2003 was classified as general and administrative expenses.

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)

	September 30, 2004 (restated)	December 31, 2003 (restated)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,944	$ 24,622
Accounts receivable, net of allowances of $8,734 at September 30, 2004 and $7,492 at December 31, 2003	57,665	55,418
Inventories	57,668	47,423
Deferred tax assets	1,178	1,178
Prepaid expenses and other current assets	10,893	10,599
Total current assets	146,348	139,240
Property, plant and equipment, net	62,645	57,773
Goodwill	222,449	216,733
Other intangible assets with indefinite lives	50,092	46,719
Core technology and patents, net	40,920	37,942
Other intangible assets, net	28,965	32,679
Deferred financing costs, net, and other non-current assets	8,795	7,457
Deferred tax assets	495	1,456
Total assets	$ 560,709	$ 539,999
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 52	$ 14,055
Current portion of capital lease obligations	458	457
Accounts payable	35,225	38,006
Accrued expenses and other current liabilities	45,066	41,122
Total current liabilities	80,801	93,640
Long-term liabilities:		
Long-term debt, net of current portion	198,128	159,838
Capital lease obligations, net of current portion	1,477	1,831
Deferred tax liabilities	11,511	9,118
Other long-term liabilities	4,981	3,307
Total long-term liabilities	216,097	174,094
Commitments and contingencies		
Series A redeemable convertible preferred stock, $0.001 par value:		
Authorized 2,667 shares		
Issued 2,527 shares at September 30, 2004 and December 31, 2003		
Outstanding none at September 30, 2004 and 208 shares at December 31, 2003		6,185
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 20,325 shares at September 30, 2004 and 19,640 shares at December 31, 2003	20	20

	September 30, 2004	December 31, 2003
Additional paid-in capital	353,060	341,703
Notes receivable from stockholders	(14,691)	(14,691)
Accumulated deficit	(86,500)	(72,765)
Accumulated other comprehensive income	11,922	11,813
Total stockholders' equity	263,811	266,080
Total liabilities and stockholders' equity	$ 560,709	$ 539,999

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)

	Nine Months Ended September 30, 2004 (restated)	Nine Months Ended September 30, 2003 (restated)
Cash Flows from Operating Activities:		
Net (loss) income	$ (12,990)	$ 8,414
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Interest expense related to amortization and/or write-off of noncash original issue discount and deferred financing costs	4,380	1,133
Noncash gains related to interest rate swap and currency hedge agreements	(326)	(54)
Noncash stock-based compensation expense		66
Depreciation and amortization	17,641	10,930
Deferred income taxes	1,922	1,514
Other noncash items	(70)	(4)
Changes in assets and liabilities, net of acquisitions:		
Accounts receivable, net	(1,717)	(3,051)
Inventories	(9,274)	(3,668)
Prepaid expenses and other current assets	(189)	(2,937)
Accounts payable	(3,386)	353
Accrued expenses and other current liabilities	6,963	(6,817)
Increase in other long-term liabilities	489	
Net cash provided by operating activities	3,443	5,879
Cash Flows from Investing Activities:		
Purchases of property, plant and equipment	(15,403)	(8,427)
Proceeds from sale of property, plant and equipment	184	151
Payments for acquisitions and intellectual property	(12,275)	(76,141)
Increase in other assets	(1,129)	(44)
Net cash used in investing activities	(28,623)	(84,461)
Cash Flows from Financing Activities:		
Cash paid for financing costs	(5,333)	(3,772)
Proceeds from issuance of common stock, net of issuance costs	1,416	3,985
Proceeds from issuance of senior subordinated notes	150,000	
Proceeds from borrowings under senior credit facility		58,643
Net (repayments) proceeds from revolving lines of credit	(31,099)	18,524
Repayments of notes payable	(94,764)	(5,875)
Principal payments of capital lease obligations	(362)	(521)
Net cash provided by financing activities	19,858	70,984
Foreign exchange effect on cash and cash equivalents	(356)	1,767
Net decrease in cash and cash equivalents	(5,678)	(5,831)
Cash and cash equivalents, beginning of period	24,622	30,668
Cash and cash equivalents, end of period	$ 18,944	$ 24,837

	Nine Months Ended September 30,	
Supplemental Disclosure of Noncash Activities:		
Dividends, redemption interest and amortization of beneficial conversion feature related to preferred stock	$ 749	$ 458
Fair value of stock issued for acquisitions and intellectual property	$ 3,002	$ 75,305
Fair value of assumed and fully-vested stock options and warrants for acquisitions	$	$ 1,752
Conversion of preferred stock into 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, 2003 included information and footnotes necessary for such presentation and were included in our annual report on Form 10-K/A, Amendment No. 3, filed with the Securities and Exchange Commission ("SEC") on February 11, 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, 2003.

In connection with our restatements for the years ended December 31, 2003 and 2002, as discussed in our 2003 annual report on Form 10-K/A, Amendment No. 3, we also restated our consolidated financial statements for the three and nine months ended September 30, 2004 and 2003, respectively, to reflect corrections to our income tax provisions and adjustments to amortization expense resulting from revisions made to our purchase price allocation in connection with our acquisition of a business from Abbott as of September 30, 2003, the acquisition date. Such adjustments are reflected in the accompanying consolidated financial statements and discussed in Note 15 herein.

(2) Cash and Cash Equivalents

We consider all highly liquid cash investments with original maturities of three months or less at the date of acquisition to be cash equivalents. At September 30, 2004, our cash equivalents consisted of money market funds.

(3) Inventories

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

(in thousands)	September 30, 2004	December 31, 2003
Raw materials	$ 24,633	$ 19,606
Work-in-process	14,212	12,631
Finished goods	18,823	14,806
	$ 57,668	$ 47,043

(4) 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) income would have been (increased) decreased to the pro forma amounts indicated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share amounts)	**2004**	**2003(b)**	**2004**	**2003(b)**
	(restated)	**(restated)**	**(restated)**	**(restated)**
Net (loss) income as reported	$ (2,262)	$ 1,281	$ (12,990)	$ 8,414
Stock-based employee compensation as reported (a)		15		16
Pro forma stock-based employee compensation	(1,563)	(1,388)	(4,368)	(3,609)
Net (loss) income pro forma	$ (3,825)	$ (92)	$ (17,358)	$ 4,821
(Loss) income per share basic:				
Net (loss) income per share as reported	$ (0.11)	$ 0.07	$ (0.69)	$ 0.54
Stock-based employee compensation as reported				
Pro forma stock-based employee compensation	(0.08)	(0.08)	(0.22)	(0.25)
Net (loss) income per share pro forma	$ (0.19)	$ (0.01)	$ (0.91)	$ 0.29
(Loss) income per share diluted:				
Net (loss) income per share as reported	$ (0.11)	$ 0.06	$ (0.69)	$ 0.48
Stock-based employee compensation as reported				
Pro forma stock-based employee compensation	(0.08)	(0.07)	(0.22)	(0.22)
Net (loss) income per share pro forma	$ (0.19)	$ (0.01)	$ (0.91)	$ 0.26

(a) Stock-based employee compensation expense, as reported, primarily represents the amortization of deferred compensation of certain stock options that were granted to employees below fair market value. This amount excludes stock-based compensation expense recognized in connection with stock options that were granted to non-employees.

(b) Pro forma stock-based employee compensation charge and related per share charge for the three and nine months ended September 30, 2003 have been adjusted to reflect estimated tax benefits associated with such charge.

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 September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Risk-free interest rate	3.4-3.5%	2.6-3.5%	2.8-4.0%	2.3-3.5%
Expected dividend yield				
Expected lives	5 years	5 years	5 years	5 years
Expected volatility	48%	53%	48%	56%

The weighted average fair value under the Black-Scholes option pricing model of options granted to employees during the three months ended September 30, 2004 and 2003 were $7.22 and $11.22, respectively. The weighted average fair value under the Black-Scholes option pricing model of options granted to employees during the nine months ended September 30, 2004 and 2003 were $8.72 and $10.34, respectively.

(5) Earnings Per Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share amounts)	**2004**	**2003**	**2004**	**2003**
	(restated)	**(restated)**	**(restated)**	**(restated)**
Numerator:				
Net (loss) income	$ (2,262)	$ 1,281	$ (12,990)	$ 8,414
Dividends, redemption interest and amortization of beneficial conversion feature related to Series A Preferred Stock		(143)	(749)	(458)
Net (loss) income available to common stockholders basic	(2,262)	1,138	(13,739)	7,956
Interest on convertible promissory notes				135
Net (loss) income available to common stockholders diluted	$ (2,262)	$ 1,138	$ (13,739)	$ 8,091

(in thousands, except per share amounts)	Three Months Ended September 30, 2004 (restated)	Three Months Ended September 30, 2003 (restated)	Nine Months Ended September 30, 2004 (restated)	Nine Months Ended September 30, 2003 (restated)
Denominator:				
Denominator for basic (loss) income per share weighted average shares	20,296	16,301	19,813	14,719
Effect of dilutive securities:				
Employee stock options		753		528
Warrants		266		193
Restricted stock and escrow shares		856		1,004
Convertible promissory notes				344
Dilutive potential common shares		1,875		2,069
Denominator for dilutive (loss) income per share adjusted weighted average shares and assumed conversions	20,296	18,176	19,813	16,788
Net (loss) income per share basic	$ (0.11)	$ 0.07	$ (0.69)	$ 0.54
Net (loss) income per share diluted	$ (0.11)	$ 0.06	$ (0.69)	$ 0.48

We had the following potential dilutive securities outstanding on September 30, 2004: (a) options and warrants to purchase an aggregate of 4.1 million shares of common stock at a weighted average exercise price of $15.96 per share and (b) 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 for the three and nine months ended September 30, 2004 because the effect of including the number of such potential dilutive securities would be antidilutive.

For the three months ended September 30, 2003, the computation of diluted income per share did not include convertible promissory notes and Series A Preferred Stock that are convertible into an aggregate of 344,000 and 646,000 shares of common stock, respectively, because the inclusion thereof, together with the add-back of interest and redemption interest, would be antidilutive. For the nine months ended September 30, 2003, the computation of diluted income per share did not include Series A Preferred Stock that are convertible into an aggregate of 646,000 shares of common stock because inclusion thereof, together with the add-back of redemption interest and dividends, would be antidilutive. We also had potential dilutive options and warrants to purchase an aggregate of 816,000 shares of common stock at a weighted average exercise price of $22.01 per share outstanding on September 30, 2003, which were not included in the computation of diluted income per share for the three and nine months ended September 30, 2003 because the inclusion thereof would be antidilutive.

(6) Series A Redeemable Convertible Preferred Stock

In January 2004, 208,000 shares of our series A redeemable convertible preferred stock ("Series A Preferred Stock") were converted into 416,000 shares of our common stock. For the nine months ended September 30, 2004, we recorded $749,000 in related redemption interest and amortization of beneficial conversion feature, along with the acceleration of the remaining unamortized beneficial conversion feature upon the Series A Preferred Stock conversion.

(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, and to a lesser extent, pension adjustments. For the three and nine months ended September 30, 2004, we generated a comprehensive loss of $2.0 million and $12.9 million, respectively, and for the three and nine months ended September 30, 2003, we generated comprehensive income of $2.3 million and $11.6 million, respectively.

(8) 8.75% Senior Subordinated Notes

On February 10, 2004, we completed the sale of $150.0 million of 8.75% senior subordinated notes (the "Bonds"), due 2012 in a private placement to qualified institutional buyers. Net proceeds from this offering amounted to $145.9 million which was net of underwriters' commissions of $4.1 million. Of the net proceeds, $125.3 million was used to repay all of the outstanding indebtedness and related financing fees under our primary senior credit facility and $9.2 million was used to prepay outstanding 9% subordinated promissory notes and related prepayment penalties. We retained the remaining unused proceeds for Bond offering expenses and general corporate purposes.

The 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 will be payable semi-annually in arrears on each February 15 and August 15, commencing on August 15, 2004. For the three and nine months ended September 30, 2004, we recorded $3.5 million and $8.8 million, respectively, in interest expense, including amortization of deferred financing costs, related to the Bonds. 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.

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

The Bonds are guaranteed by all of our domestic subsidiaries that are guarantors or borrowers under the senior credit facility which, as of September 30, 2004, excluded our subsidiary IVC Industries, Inc. (d/b/a Inverness Medical Nutritionals Group or "IMN"). On October 20, 2004, IMN was designated as an additional guarantor under the Bonds (Note 14). 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 senior credit facilities. See Note 16 for guarantor financial information.

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, pay dividends or make other distributions or repurchase or redeem 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.

In connection with the prepayment of the outstanding balances under our primary senior credit facility and 9% subordinated promissory notes, we recorded additional interest expense of $3.8 million for the nine months ended September 30, 2004, which consisted of a write-off of the remaining related unamortized deferred financing costs of $3.2 million, a financing fee of $450,000 paid to the banks in connection with our repayment of borrowings under our senior credit facility and a prepayment penalty of $180,000, which equated to 2% of the principal balance repaid under our 9% subordinated promissory notes.

(9) Business Combinations

(a) Recent Acquisitions

On June 16, 2004, we acquired Advantage Diagnostics Corporation ("ADC"), a closely held lateral flow diagnostic company that specializes in rapid test development and component manufacturing. The purchase price consisted of $2.4 million in cash and $216,000 in assumed debt. The terms of the merger agreement also provide for $1.5 million of contingent consideration payable to the ADC shareholders, upon the successful completion of a new product under development by December 31, 2005.

On June 2, 2004, we acquired Viva Diagnostika ("Viva"), a closely held distributor of professional diagnostic products to the German marketplace. The purchase price of Viva consisted of $2.6 million in cash, 155,000 shares of our common stock with an aggregate fair value of $3.0 million and $295,000 in assumed debt.

(b) Restructuring Plans of Previous Acquisitions

In connection with our acquisitions of Ostex International, Inc. ("Ostex"), 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 Emerging Issues Task Force ("EITF") Issue No. 95-3, *Recognition of Liabilities in Connection with a Purchase Business Combination*. The following table sets forth the restructuring cost balances related to the restructuring activities of these acquired businesses as of September 30, 2004 and the activities in these accounts during the nine months ended September 30, 2004:

(in thousands)	Balance at December 31, 2003	Net Costs Added to Purchase Price	Amounts Paid	Other (1)	Balance at September 30, 2004
Ostex	$ 2,086	$ 309	$ (1,432)	$	$ 963
IMN	519		(237)		282
Unipath business	1,347			15	1,362
Total restructuring costs	$ 3,952	$ 309	$ (1,669)	$ 15	$ 2,607

(1) Represents foreign currency translation adjustment.

As a result of our acquisition of Ostex in June 2003, we established a restructuring plan whereby we exited the facilities of Ostex in Seattle, Washington, and combined such activities with our existing manufacturing and distribution facilities. Total severance costs associated with involuntarily terminated employees are $1.6 million, of which substantially all has been paid as of September 30, 2004. Costs to vacate the Ostex facilities are $500,000, of which $125,000 has been paid as of September 30, 2004. Additionally, the remaining costs to exit operations, primarily facilities lease commitments, are $1.9 million, of which $1.3 million has been paid as of September 30, 2004.

In connection with our IMN acquisition in March 2002, 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. 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 involuntarily terminated employees and costs to vacate the warehouse, $1.3 million have been paid as of September 30, 2004.

As a result of our acquisition of the Unipath business in December 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 most major cost centers at the operations of the Unipath England location. Additionally, most business activities of the division in the United States were merged into our existing U.S. businesses. Total exit costs, which primarily related to severance and early retirement obligations, amounted to $4.2 million. As of September 30, 2004, $1.4 million of these exit costs remained unpaid.

(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 September 30,		Nine Months Ended September 30,	
(in thousands)	**2004**	**2003**	**2004**	**2003**
Service cost	$ 449	$ 334	$ 1,349	$ 1,004
Interest cost	51	14	154	42
Expected return on plan assets	(45)	(14)	(136)	(43)
Realized losses	5		16	
Net periodic benefit costs	$ 460	$ 334	$ 1,383	$ 1,003

(11) Restructuring Plan

During the three and nine months ended September 30, 2004, we recorded a $1.7 million restructuring charge included in cost of goods sold to cover all expected severance, early retirement and outplacement services arising from a recently completed plan of termination at our manufacturing facility in Bedford, England. Of the total restructuring charge, $1.5 million and $0.2 million was included in our consumer products and professional diagnostic products business segments, respectively. As of September 30, 2004, all restructuring costs remained unpaid.

(12) 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 our chief executive officer and members of our senior management. Our reportable operating segments are Consumer Products (comprised of consumer diagnostic products and vitamins and nutritional supplements), Professional Diagnostic Products, and Corporate and Other.

We evaluate performance based on revenue and earnings before taxes. Segment information for the three and nine months ended September 30, 2004 and 2003, respectively, is as follows:

(in thousands)	Consumer Products	Professional Diagnostic Products	Corporate and Other	Total
Three Months Ended September 30, 2004				
Net revenue from external customers	$ 64,263	$ 33,242	$	$ 97,505
Income (loss) before income taxes (restated)	6,203	(289)	(6,974)	(1,060)
Three Months Ended September 30, 2003				
Net revenue from external customers	50,222	22,171		72,393
Income (loss) before income taxes	3,218	2,337	(3,501)	2,054
Nine Months Ended September 30, 2004				
Net revenue from external customers	181,325	95,608		276,933
Income (loss) before income taxes (restated)	11,843	(237)	(21,472)	(9,866)
Nine Months Ended September 30, 2003 (restated)				
Net revenue from external customers	147,381	55,831		203,212
Income (loss) before income taxes	13,349	5,542	(7,315)	11,576
Assets at September 30, 2004 (restated)	289,104	265,812	5,793	560,709
Assets at December 31, 2003 (restated)	281,148	254,756	4,095	539,999

(13) Material Contingencies

Our material pending legal proceedings are described in the section of our annual report on Form 10-K/A for the year ended December 31, 2003 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."

(14) Subsequent Event

In October 2004, we borrowed an additional $15.2 million under our senior credit facility to refinance the outstanding borrowings under IMN's senior credit facility and bonds payable. We repaid all outstanding borrowings under IMN's senior credit facility which totaled $14.2 million as of the date of repayment, including a $150,000 prepayment penalty, and redeemed $1.5 million of IMN's outstanding bonds payable. As of October 20, 2004, IMN became a credit party under our senior credit facility and was designated a restricted subsidiary and guarantor under the Bonds. IMN is considered a non-guarantor subsidiary in the guarantor financial information in Note 15 and will be included as a guarantor subsidiary going forward.

(15) Restatements

In connection with our restatements for the years ended December 31, 2003 and 2002, as discussed in our 2003 annual report on Form 10-K/A, Amendment No. 3, we also restated our previously issued consolidated financial statements as of September 30, 2004 and for the three and nine months ended September 30, 2004 and 2003, respectively, to correct an error in the calculation of the provisions for income taxes and the related deferred tax accounts. We should have reported gross, certain deferred tax liabilities associated with temporary differences related to differing tax and book bases of goodwill and other intangible assets. As a result, we have recorded an additional valuation allowance against the deferred tax assets associated with certain net operating loss carry forwards. The correction of this error resulted in incremental non-cash provisions of income taxes in the amount of $640,000 for the third quarter of 2004. In addition, we revised the purchase price allocation in connection with our acquisition of certain assets from Abbott Laboratories (the "Abbott business") on September 30, 2003 to attribute $5.7 million to customer related intangible assets acquired in the acquisition. We have also recorded and commenced to amortize as of the date of the acquisition $11.3 million of other assets acquired from Abbott, the amortization of which amounted to approximately $51,000 per quarter, that it had originally recognized in our Quarterly Report on Form 10-Q for the period ended September 30, 2004. Goodwill generated in connection with the acquisition of the Abbott business is reduced by these amounts. The impact of this revision of the purchase price allocation is to increase amortization expense by $851,000 for the third quarter of 2004. The restatements as a result of the error in the calculation of the provision for income taxes and related deferred tax accounts and the revision of the purchase price allocation in connection with the acquisition of the Abbott business and the resultant incremental amortization are reflected in the amounts below as "as restated."

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 income (loss) from continuing operations, net income (loss) and income (loss) per share. All applicable amounts relating to the aforementioned restatements have been reflected in these consolidated financial statements and notes hereto.

	Three Months Ended September 30, 2004		Three Months Ended September 30, 2003	
	As restated	As reported	As restated	As reported
	(in thousands, except per share amounts)			
Cost of sales	$ 59,171	$ 59,120	$ *	$ *
Sales and marketing	14,824	14,024	*	*
Income tax provision	1,202	562	773	392
Net (loss) income	(2,262)	(771)	1,281	1,662
Net (loss) income per common share basic	$ (0.11)	$ (0.04)	$ 0.07	$ 0.09
Net (loss) income per common share diluted	(0.11)	(0.04)	$ 0.06	0.08

	Nine Months Ended September 30, 2004		Nine Months Ended September 30, 2003	
	As restated	As reported	As restated	As reported
	(in thousands, except per share amounts)			
Cost of sales	$ 166,686	$ 166,533	$ *	$ *
Sales and marketing	42,836	40,437	*	*
Income tax provision	3,124	1,202	3,162	2,019
Net (loss) income	(12,990)	(8,516)	8,414	9,557
Net (loss) income per common share basic	$ (0.69)	$ (0.47)	$ 0.54	$ 0.62
Net (loss) income per common share diluted	(0.69)	(0.47)	$ 0.48	0.55

	September 30, 2004		December 31, 2003	
	As restated	As reported	As restated	As reported
	(in thousands)			
Inventories	$ *	$ *	$ 47,423	$ 47,043
Property, plant and equipment, net	*	*	57,773	56,999
Goodwill	222,449	228,184	216,733	233,792
Other intangible assets with indefinite lives	*	*	46,719	38,119
Core technology and patents, net	40,920	41,124	37,942	36,423
Other intangible assets, net	28,965	26,428	32,679	27,743
Deferred tax assets, non-current	495	5,036	1,456	4,075
Accumulated deficit	(86,500)	(78,557)	(72,765)	(69,296)

*

These accounts were not restated.

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

(16) Guarantor Financial Information

We issued $150 million in 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 (Note 8). Our payment obligations under the Bonds are guaranteed by certain 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 for the three and nine months ended September 30, 2004 and 2003, the balance sheets as of September 30, 2004 and December 31, 2003 and the statements of cash flows for the nine months ended September 30, 2004 and 2003 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 third parties.

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF OPERATIONS
For the Three Months Ended September 30, 2004
(unaudited)
(restated)
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	$ 5,524	$ 43,552	$ 61,463	$ (15,841)	$ 94,698
License revenue		37	2,770		2,807
Net revenue	5,524	43,589	64,233	(15,841)	97,505
Cost of sales	5,212	27,624	40,901	(14,566)	59,171
Gross profit	312	15,965	23,332	(1,275)	38,334
Operating expenses:					
Research and development	81	763	7,006		7,850
Sales and marketing	466	5,176	9,182		14,824
General and administrative	2,324	2,323	8,406		13,053
Total operating expenses	2,871	8,262	24,594		35,727
Operating (loss) income	(2,559)	7,703	(1,262)	(1,275)	2,607
Equity in earnings of subsidiaries, net of tax	3,753			(3,753)	
Interest expense, including amortization of discounts and write off of deferred financing costs	(4,268)	(198)	(1,494)	1,114	(4,846)
Other income, net	1,151	127	1,015	(1,114)	1,179
(Loss) income before income taxes	(1,923)	7,632	(1,741)	(5,028)	(1,060)
Income tax provision	339	480	383		1,202
Net (loss) income	$ (2,262)	$ 7,152	$ (2,124)	$ (5,028)	$ (2,262)

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF OPERATIONS
For the Three Months Ended September 30, 2003
(unaudited)
(restated)
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	$ 5,894	$ 27,401	$ 48,332	$ (12,349)	$ 69,278
License revenue		147	2,968		3,115
Net revenue	5,894	27,548	51,300	(12,349)	72,393
Cost of sales	5,280	17,738	28,154	(10,270)	40,902
Gross profit	614	9,810	23,146	(2,079)	31,491
Operating expenses:					
Research and development	67	592	5,754		6,413
Sales and marketing	449	5,738	7,064		13,251
General and administrative	1,743	1,680	4,214		7,637
Stock-based compensation	60				60
Total operating expenses	2,319	8,010	17,032		27,361
Operating (loss) income	(1,705)	1,800	6,114	(2,079)	4,130
Equity in earnings of subsidiaries, net of tax	3,834			(3,834)	
Interest expense, including amortization of discounts	(1,126)	(398)	(1,435)	516	(2,443)
Other income, net	377	349	157	(516)	367
Income before income taxes	1,380	1,751	4,836	(5,913)	2,054
Income tax provision	99	235	439		773
Net income	$ 1,281	$ 1,516	$ 4,397	$ (5,913)	$ 1,281

19

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF OPERATIONS
For the Nine Months Ended September 30, 2004
(unaudited)
(restated)
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	$ 15,453	$ 113,382	$ 179,565	$ (38,771)	$ 269,629
License revenue		83	7,221		7,304
Net revenue	15,453	113,465	186,786	(38,771)	276,933
Cost of sales	14,979	75,418	115,491	(39,202)	166,686
Gross profit	474	38,047	71,295	431	110,247
Operating expenses:					
Research and development	181	2,278	20,806		23,265
Sales and marketing	1,483	17,106	24,247		42,836
General and administrative	7,851	9,090	21,569		38,510
Total operating expenses	9,515	28,474	66,622		104,611
Operating (loss) income	(9,041)	9,573	4,673	431	5,636
Equity in earnings of subsidiaries, net of tax	4,989			(4,989)	
Interest expense, including amortization of discounts and write off of deferred financing costs	(11,255)	(4,236)	(4,383)	2,717	(17,157)
Other income, net	2,880	373	1,119	(2,717)	1,655
(Loss) income before income taxes	(12,427)	5,710	1,409	(4,558)	(9,866)
Income tax provision	563	1,713	848		3,124
Net (loss) income	$ (12,990)	$ 3,997	$ 561	$ (4,558)	$ (12,990)

20

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF OPERATIONS
For the Nine Months Ended September 30, 2003
(unaudited)
(restated)
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	$ 17,613	$ 71,734	$ 139,812	$ (32,977)	$ 196,182
License revenue		178	6,852		7,030
Net revenue	17,613	71,912	146,664	(32,977)	203,212
Cost of sales	14,710	44,990	84,171	(30,654)	113,217
Gross profit	2,903	26,922	62,493	(2,323)	89,995
Operating expenses:					
Research and development	204	871	15,980		17,055
Sales and marketing	1,567	16,299	19,083		36,949
General and administrative	5,299	4,176	14,538		24,013
Stock-based compensation	66				66
Total operating expenses	7,136	21,346	49,601		78,083
Operating (loss) income	(4,233)	5,576	12,892	(2,323)	11,912
Equity in earnings of subsidiaries, net of tax	11,188			(11,188)	
Interest expense, including amortization of discounts	(3,091)	(986)	(3,458)	812	(6,723)
Other income (expense), net	4,899	(627)	2,927	(812)	6,387
Income before income taxes	8,763	3,963	12,361	(13,511)	11,576
Income tax provision	349	1,138	1,490	185	3,162
Net income	$ 8,414	$ 2,825	$ 10,871	$ (13,696)	$ 8,414

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING BALANCE SHEET
September 30, 2004
(unaudited)
(restated)
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
ASSETS					
Current Assets:					
Cash and cash equivalents	$ 232	$ 7,240	$ 11,472	$	$ 18,944
Accounts receivable, net of allowances	2,110	31,759	23,796		57,665
Inventories	5,862	20,960	36,738	(5,892)	57,668
Deferred tax assets			1,178		1,178
Prepaid expenses and other current assets	2,372	1,627	6,894		10,893
Intercompany receivables	56,713	12,925	13,933	(83,571)	
Total current assets	67,289	74,511	94,011	(89,463)	146,348
Property, plant and equipment, net	3,106	11,381	48,158		62,645
Goodwill	29,538	96,178	96,733		222,449
Other intangible assets with indefinite lives		12,420	37,672		50,092
Core technology and patents, net	2,611	5,832	32,477		40,920
Other intangible assets, net	5,918	15,184	7,863		28,965
Deferred financing costs, net, and other non-current assets	6,176	1,573	1,046		8,795
Deferred tax assets	(632)	(2,157)	2,826	458	495
Investment in subsidiaries	235,676	(868)		(234,808)	
Intercompany notes receivable	109,403	13,563		(122,966)	
Total assets	$ 459,085	$ 227,617	$ 320,786	$ (446,779)	$ 560,709
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Current portion of long-term debt	$	$	$ 52	$	$ 52
Current portion of capital lease obligations		2	456		458
Accounts payable	1,160	9,039	25,026		35,225
Accrued expenses and other current liabilities	8,109	13,351	23,606		45,066
Intercompany payables	10,799	14,204	58,568	(83,571)	
Total current liabilities	20,068	36,596	107,708	(83,571)	80,801
Long-term liabilities:					
Long-term debt, net of current portion	175,206	9,700	13,222		198,128
Capital lease obligations, net of current portion		5	1,472		1,477
Deferred tax liabilities		1,753	9,758		11,511
Other long-term liabilities			4,981		4,981
Intercompany notes payable		58,389	64,621	(123,010)	
Total long-term liabilities	175,206	69,847	94,054	(123,010)	216,097
Stockholders' equity	263,811	121,174	119,024	(240,198)	263,811

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Total liabilities and stockholders' equity	$ 459,085	$ 227,617	$ 320,786	$ (446,779)	$ 560,709

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING BALANCE SHEET
December 31, 2003
(restated)
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
ASSETS					
Current Assets:					
Cash and cash equivalents	$ 1,708	$ 11,058	$ 11,856	$	$ 24,622
Accounts receivable, net of allowances	3,915	29,505	21,998		55,418
Inventory	4,463	19,737	29,360	(6,137)	47,423
Deferred tax assets			1,178		1,178
Prepaid expenses and other current assets	1,365	1,507	7,727		10,599
Intercompany receivables	6,073	11,785	8,911	(26,769)	
Total current assets	17,524	73,592	81,030	(32,906)	139,240
Property, plant and equipment, net	1,199	10,405	46,169		57,773
Goodwill	48,704	73,188	94,841		216,733
Trademarks and trade name with indefinite lives		9,092	37,627		46,719
Core technology and patents, net	8,193	293	29,456		37,942
Other intangible assets, net	6,437	15,400	10,842		32,679
Deferred financing costs, net, and other assets	2,015	4,150	1,292		7,457
Deferred tax assets	(295)	(571)	2,322		1,456
Investment in subsidiaries	204,553			(204,553)	
Intercompany notes receivable	120,918	94,208		(215,126)	
Total assets	$ 409,248	$ 279,757	$ 303,579	$ (452,585)	$ 539,999
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Current portion of long-term debt	$	$	$ 14,055	$	$ 14,055
Current portion of capital lease obligations		18	439		457
Accounts payable	4,448	11,431	22,127		38,006
Accrued expenses and other current liabilities	8,641	14,879	17,602		41,122
Intercompany payables	6,512	8,036	12,226	(26,774)	
Total current liabilities	19,601	34,364	66,449	(26,774)	93,640
Long-term liabilities:					
Long-term debt	34,056	91,974	33,808		159,838
Capital lease obligations		20	1,811		1,831
Deferred tax liabilities		1,752	7,366		9,118
Other liabilities			3,307		3,307
Intercompany notes payable	83,326	57,186	74,611	(215,123)	
Total long-term liabilities	117,382	150,932	120,903	(215,123)	174,094

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Series A redeemable convertible preferred stock	6,185				6,185
Stockholders' equity	266,080	94,461	116,227	(210,688)	266,080
Total liabilities and stockholders' equity	$ 409,248	$ 279,757	$ 303,579	$ (452,585)	$ 539,999

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF CASH FLOWS
For the Nine Months Ended September 30, 2004
(unaudited)
(restated)
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Operating Activities:					
Net (loss) income	$ (12,990)	$ 3,997	$ 561	$ (4,558)	$ (12,990)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:					
Equity in earnings of subsidiaries, net of tax	(4,989)			4,989	
Interest expense related to amortization and/or write-off of non-cash original issue discount, and deferred financing costs	843	3,145	392		4,380
Noncash (gains) losses related to interest rate swap and currency hedge agreements	(432)		106		(326)
Depreciation and amortization	1,135	3,661	12,845		17,641
Deferred income taxes	336	1,586			1,922
Other noncash items		2	(72)		(70)
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net	1,805	(3,101)	(421)		(1,717)
Inventories	(1,399)	(1,152)	(6,292)	(431)	(9,274)
Prepaid expenses and other current assets	(1,008)	(134)	953		(189)
Intercompany payables or receivables	10,443	(10,274)	(248)	79	
Accounts payable	(3,290)	(2,449)	2,353		(3,386)
Accrued expenses and other current liabilities	2,301	(1,152)	5,814		6,963
Increase in other long-term liabilities			489		489
Net cash (used in) provided by operating activities	(7,245)	(5,871)	16,480	79	3,443

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF CASH FLOWS (continued)
For the Nine Months Ended September 30, 2004
(unaudited)
(restated)
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Investing Activities:					
Purchases of property, plant and equipment	(1,531)	(5,056)	(8,816)		(15,403)
Proceeds from sale of property, plant and equipment		123	61		184
Payments for acquisitions and intellectual property	(4,713)	(1,570)	(5,992)		(12,275)
(Increase) decrease in other assets	(748)	(689)	308		(1,129)
Net cash used in investing activities	(6,992)	(7,192)	(14,439)		(28,623)
Cash Flows from Financing Activities:					
Cash paid for financing costs	(4,846)	(391)	(96)		(5,333)
Proceeds from issuance of common stock, net of issuance costs	1,416				1,416
Proceeds from issuance of senior subordinated notes	150,000				150,000
Net repayments under revolving lines of credit		(7,199)	(23,900)		(31,099)
Repayments of notes payable	(9,000)	(75,075)	(10,689)		(94,764)
Principal payments of capital lease obligations		(39)	(323)		(362)
Intercompany notes payable or receivable	(124,809)	91,949	32,860		
Net cash provided by (used in) financing activities	12,761	9,245	(2,148)		19,858
Foreign exchange effect on cash and cash equivalents			(277)	(79)	(356)
Net decrease in cash and cash equivalents	(1,476)	(3,818)	(384)		(5,678)
Cash and cash equivalents, beginning of period	1,708	11,058	11,856		24,622
Cash and cash equivalents, end of period	$ 232	$ 7,240	$ 11,472	$	$ 18,944

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF CASH FLOWS
For the Nine Months Ended September 30, 2003
(unaudited)
(restated)
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Operating Activities:					
Net income (loss)	$ 8,414	$ 2,825	$ 10,871	$ (13,696)	$ 8,414
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:					
Equity in earnings (losses) of subsidiaries, net of tax	(11,188)			11,188	
Interest expense related to amortization of noncash original issue discount and deferred financing costs	319	280	534		1,133
Noncash gain related to interest rate swap agreement	(54)				(54)
Noncash stock-based compensation expense	66				66
Depreciation and amortization	587	2,084	8,259		10,930
Deferred income taxes	336	807	186	185	1,514
Other noncash items		(27)	23		(4)
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net	(322)	(2,311)	(418)		(3,051)
Inventories	25	(3,389)	(3,063)	2,759	(3,668)
Prepaid expenses and other current assets	(526)	693	(3,104)		(2,937)
Intercompany payables or receivables	(3,349)	359	4,853	(1,863)	
Accounts payable	128	2,770	(2,545)		353
Accrued expenses and other current liabilities	358	(3,379)	(3,796)		(6,817)
Net cash (used in) provided by operating activities	(5,206)	712	11,800	(1,427)	5,879

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF CASH FLOWS (continued)
For the Nine Months Ended September 30, 2003
(unaudited)
(restated)
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Investing Activities:					
Purchases of property, plant and equipment	(262)	(1,658)	(6,507)		(8,427)
Proceeds from sale of property, plant and equipment		73	78		151
Payments for acquisitions and intellectual property	(70,296)	(2,342)	(3,503)		(76,141)
Decrease (increase) in other assets	718	(708)	(54)		(44)
Net cash used in investing activities	(69,840)	(4,635)	(9,986)		(84,461)
Cash Flows from Financing Activities:					
Cash paid for financing costs	(86)	(3,637)	(49)		(3,772)
Proceeds from issuance of common stock, net of issuance costs	3,985				3,985
Proceeds from borrowings under senior credit facility		57,575	1,068		58,643
Net proceeds from lines of credit		16,899	1,625		18,524
Repayments of notes payable		(3,271)	(2,604)		(5,875)
Principal payments of capital lease obligations		(5)	(516)		(521)
Intercompany notes payable or receivable	68,400	(68,400)			
Net cash provided by (used in) financing activities	72,299	(839)	(476)		70,984
Foreign exchange effect on cash and cash equivalents			340	1,427	1,767
Net (decrease) increase in cash and cash equivalents	(2,747)	(4,762)	1,678		(5,831)
Cash and cash equivalents, beginning of period	3,004	16,069	11,595		30,668
Cash and cash equivalents, end of period	$ 257	$ 11,307	$ 13,273	$	$ 24,837

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 new product launches, research and development expenditures, legal expenditures, benefits to be realized as a result of synergies relating to our acquisitions, net product sales and gross profits from our various business segments, license revenue, 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.

Overview

We are a leading global developer, manufacturer and marketer of in vitro diagnostic products for the over-the-counter pregnancy and fertility/ovulation test market and the professional rapid diagnostic test market. In addition, we manufacture a variety of vitamins and nutritional supplements that we market under our brands and those of private label retailers in the consumer market primarily in the United States.

Our business is organized into two primary segments, consumer products and professional diagnostic products. The consumer products segment includes our over-the-counter pregnancy and fertility/ovulation tests and vitamins and nutritional supplements. The professional diagnostic products segment includes an array of innovative rapid diagnostic test products and other in vitro diagnostic tests marketed to medical professionals and laboratories for detection of infectious diseases, drugs of abuse and pregnancy.

For the three and nine months ended September 30, 2004, we recorded net revenue of $97.5 million and $276.9 million, respectively, compared to net revenue of $72.4 million and $203.2 million for the three and nine months ended September 30, 2003, respectively. Adjusted for the impact of currency translation, net revenue for the three and nine months ended September 30, 2004 was $95.1 million and $269.2 million, respectively. Overall revenue growth, adjusted for the impact of currency translation, resulted from acquisitions, which occurred primarily in our professional diagnostics business and, to a lesser extent, organic growth. Our acquisitions in the second half of 2003, including our acquisition of the rapid diagnostics business from Abbott Laboratories in September, which is discussed further below, and Applied Biotech, Inc., or ABI, in August, contributed approximately 64% of our currency adjusted revenue growth for the nine months ended September 30, 2004.

Despite the growth in our revenue, for the three and nine months ended September 30, 2004, we recorded a net loss of $2.3 million and $13.0 million, respectively, compared to net income of $1.3 million and $8.4 million for the three and nine months ended September 30, 2003, respectively. Factors that contributed to the significant loss for the nine month period ended September 30, 2004, as compared to the income in the comparable period of 2003, include (i) reduction of approximately 189 basis points in our overall gross margin due to fluctuations in foreign currencies that are unfavorable to our core pregnancy product margins, (ii) reduction of approximately 180 basis points in our overall gross margin due to margin erosion in our nutritionals business, (iii) significant research and development spending, (iv) higher interest expense due to both higher average debt balance and weighted average interest rate primarily resulted from our decision to refinance our debt in February 2004, (v) the recording of a reserve for potential bad debt and unsaleable inventory totaling

$1.5 million and (vi) the recording of a $1.7 million restructuring charge included in cost of goods sold to cover all expected severance, early retirement and outplacement services arising from a recently completed plan of termination at our manufacturing facility in Bedford, England. Partially offsetting these adverse changes was the recording of $0.5 million during the third quarter of 2004 in royalties received attributable to periods prior to 2004 associated with a license arrangement that had historically been underpaid. Additionally, the income recorded for the nine months ended September 30, 2003 included a one-time recording of income of $3.8 million from a settlement with Unilever Plc in the second quarter of 2003 and $1.2 million in past royalties received as part of a patent infringement settlement in May 2003, both of which were recorded in other income in the consolidated statements of operations in those periods.

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. We have recently executed several new point-of-care national distribution agreements and launched a new Clinical Laboratories Improvement Act of 1988 ("CLIA") waived strep throat test and tests for D-Dimer and Fecal Occult Blood and we expect to introduce a pro-thrombin meter in the first half of 2005. Our emphasis on new product development requires substantial investment and involves significant inherent risk. We intend to continue our robust research and development expenditures. In addition, we will continue to aggressively defend our substantial intellectual property portfolio, which underlies our emphasis on new product development, against potential infringers. The risks arising from our emphasis and reliance on new product development and intellectual property, as well as the other numerous risks that our business faces, including the risks associated with our substantial indebtedness and our acquisitions, are set forth in the section of this report titled "Certain Factors Affecting Future Results."

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. The operating synergies will be achieved through 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. These benefits will arise both from efficiencies related to increased volume but also in part from the redesign of the products. The marketing synergies arise as we leverage 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 accounted for 50 basis points of the reductions in sales and marketing expense as a percentage of sales for each of the three and nine month periods ended September 30, 2004 reported below in the section entitled "Results of Operations Sales and Marketing Expense."

With respect to manufacturing synergies, during the current quarter we transitioned the manufacturing of a portion 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 $300,000 on Signify product sales during the quarter as compared to the previous quarter.

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 anticipated late in the first quarter of 2005 for all countries except Japan, where the transition will occur in the forth quarter of 2005. We currently anticipate achieving synergies in line with our expectations as of the date of acquisition. Additional manufacturing synergies are 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 anticipate transitioning the vast majority of production of Fact plus for the international markets in the fourth quarter of 2004 and continue to expect to realize the manufacturing synergies anticipated at the date of acquisition. 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 titled "Certain Factors Affecting Future Results" and "Special Statement Regarding Forward-Looking Statements."

Restatements

In connection with our restatements for the years ended December 31, 2003 and 2002, as discussed in our 2003 annual report on Form 10-K/A, Amendment No. 3, we also restated our consolidated financial statements for the three and nine months ended September 30, 2004 and 2003, respectively, to reflect corrections to our income tax provisions. Such adjustments are reflected in the accompanying consolidated interim financial information for the three and nine months ended September 30, 2004 and 2003, respectively, and discussed in Note 15 hereto.

Results of Operations

Net Product Sales. Net product sales increased by $25.4 million, or 37%, to $94.7 million for the three months ended September 30, 2004 from $69.3 million for the three months ended September 30, 2003. Net product sales increased by $73.4 million, or 37%, to $269.6 million for the nine months ended September 30, 2004 from $196.2 million for the nine months ended September 30, 2003. Adjusted for the favorable impact of currency translation on our foreign operations, net product sales in the three and nine months ended September 30, 2004 grew by approximately $23.0 million, or 33%, and $65.7 million, or 33%, respectively, compared to the same periods in 2003. The majority of the product sales increase, comparing the three and nine months ended September 30, 2004 to the three and nine months ended September 30, 2003, resulted from the businesses we acquired in the second half of 2003: (i) the rapid diagnostic product lines from Abbott, which contributed $9.1 million and $28.3 million of such increase in the respective periods, and (ii) ABI, which we acquired on August 27, 2003, contributed $2.1 million and $14.0 million of such increase in the respective periods. The launch of our Clearblue Easy Digital pregnancy test in June 2003 and the commencement of our supply of the digital version of Pfizer's e.p.t pregnancy test in December 2003 and the visual version of Pfizer's e.p.t pregnancy test and the Clearblue Easy Digital ovulation test in June 2004, contributed to the currency adjusted net product sales increase, comparing the three and nine months ended September 30, 2004 to the same periods in 2003.

Net Product Sales by Business Segment. Net product sales by business segment for the three and nine months ended September 30, 2004 and 2003, respectively, are as follows:

(in thousands)	Three Months ended September 30, 2004	Three Months ended September 30, 2003	% Increase	Nine Months ended September 30, 2004	Nine Months ended September 30, 2003 (restated)	% Increase
Consumer products	$ 62,596	$ 47,641	31%	$ 176,645	$ 141,772	25%
Professional diagnostic products	32,102	21,637	48%	92,984	54,410	71%
Total net product sales	$ 94,698	$ 69,278	37%	$ 269,629	$ 196,182	37%

The currency adjusted increase in net product sales from our consumer products, which includes our consumer diagnostic products and our vitamins and nutritional supplements, was $12.5 million and $27.1 million, comparing the three and nine months ended September 30, 2004, respectively, to the same periods in 2003. Of the currency adjusted increase in the three- and nine-month period comparison, $3.1 million and $8.5 million, respectively, resulted from our acquisition of Abbott's Fact plus line of consumer diagnostic pregnancy tests. The acquisition of ABI contributed $0.7 million of the currency adjusted increase in the nine month period comparison.

The increase in net product sales from our professional diagnostic products was $10.5 million and $38.6 million, comparing the three and nine months ended September 30, 2004, respectively, to the same periods in 2003. Our acquisition of the Abbott TestPack, Abbott TestPack plus and Signify product lines from Abbott contributed $6.0 million and $19.7 million, respectively, of the increase in the three- and nine-month period comparison. Our acquisition of ABI contributed $2.6 million and $13.3 million, respectively, of the increase in the three- and nine-month period comparison. The remaining increase in net product sales from our professional diagnostic products primarily resulted from our organic growth. We expect our professional diagnostics business to continue to grow as we recently signed several new point-of-care national distribution agreements and as we have recently introduced new products, such as a CLIA waived strep throat test and tests for D-Dimer and Fecal Occult Blood, and we plan to introduce a pro-thrombin meter during the first half of 2005.

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 10%, to $2.8 million for the three months ended September 30, 2004 from $3.1 million for the three months ended September 30, 2003 and increased by $0.3 million, or 4%, to $7.3 million for the nine months ended September 30, 2004 from $7.0 million for the nine months ended September 30, 2003. The changes are a function of the net results of royalties collected under new licenses and decrease in royalties under expired licenses. We expect license revenue for the fourth quarter of 2004 to decrease, compared to the third quarter of this year, as we will cease collection of royalty fees from Pfizer early in the fourth quarter of 2004, which we have been collecting since June 2003 as part of the settlement of our infringement litigation against it.

Gross Profit and Margin. Gross profit increased by $6.8 million, or 22%, to $38.3 million for the three months ended September 30, 2004 from $31.5 million for the three months ended September 30, 2003. Gross profit increased by $20.3 million, or 23%, to $110.3 million for the nine months ended September 30, 2004 from $90.0 million for the nine months ended September 30, 2003. Included in cost of goods sold during the three and nine month period ended September 30, 2004 was a $1.7 million restructuring charge covering all expected severance, early retirement and outplacement services arising from a recently completed plan of termination at our manufacturing facility in Bedford, England. Excluding this charge, gross profit increased by $8.6 million, or 27%, to $40.1 million for the three months ended September 30, 2004 and by $22.1 million, or 25%, to $112.1 million for the nine months ended September 30, 2004.

The gross profit increase, comparing the three and nine months ended September 30, 2004 to the three and nine months ended September 30, 2003, resulted from the businesses that we acquired in the second half of 2003: (i) the rapid diagnostics business from Abbott, which contributed $4.1 million and $13.9 million of such increase in the respective periods and which gross margin increased in the third quarter of 2004 over prior quarter by approximately $0.3 million as a result of our transitioning the manufacturing of a portion of the Signify product from a third party manufacturer to our own manufacturing facility, and (ii) ABI, which contributed $0.5 million and $4.3 million of such increase. The increased profitability arising from our transition of production of Signify to our own manufacturing is attributable to synergies that we expected to benefit from when we acquired the Abbott rapid diagnostics business, and we expect to recognize additional benefits as we continue to transition production of Fact plus and commence transition of TestPack to our own facilities. Although organic growth, primarily as a result of the launch of our Clearblue Easy Digital pregnancy and ovulation tests, the commencement of our supply of the digital and visual version of Pfizer's e.p.t pregnancy tests and the growth in our professional diagnostics base business, also contributed to the increase in our overall gross profit, such increases were offset by declining profits from our nutritional supplements business. Gross profit from our nutritional supplements business, principally the private label business, declined by $1.5 million and $4.0 million, comparing the three and nine months ended September 30, 2004 to the three and nine months ended September 30, 2003, respectively, while sales of nutritional supplements increased. Our private label nutritional supplements business has suffered from excess capacity in the industry which led to increasing price competition.

Overall gross margin was 39% and 40% for the three and nine months ended September 30, 2004, respectively, compared to 44% for both the three and nine months ended September 30, 2003. The restructuring charge recorded in the third quarter of 2004 as discussed above, had the effect of reducing gross margin by 177 and 62 basis points for the three and nine months ended September 30, 2004, respectively. Gross margin was adversely impacted in 2004 by the continuing weak U.S. Dollar against the Euro and British Pound Sterling. Such movements in foreign exchange currencies negatively impacted the gross margin percentage of our products manufactured at our European subsidiaries and sold in U.S. Dollars. This currency impact had the effect of reducing gross margins by 245 and 189 basis points, comparing the three and nine months ended September 30, 2004 to the three and nine months ended September 30, 2003, respectively. Further, due to competitive pricing in the nutritional supplements business, gross margin from our nutritional supplements sales, principally in our private label business, has declined significantly. For the three and nine months ended September 30, 2004, as compared to the same periods in 2003, the margin erosion of the nutritional supplements business affected our overall gross margin by 170 and 180 basis points, respectively. Lastly, the decline in overall gross margin resulted from the ABI products, which on average have been generating lower gross margins than our other products.

Gross Profit from Net Product Sales by Business Segment. Gross profit from net product sales represents total gross profits less gross profits associated with license revenue. Gross profit from total net product sales increased by $7.1 million, or 24%, to $36.3 million for the three months ended September 30, 2004 from $29.2 million for the three months ended September 30, 2003. Gross profit from total net product sales increased by $20.0 million, or 23%, to $105.4 million for the nine months ended September 30, 2004 from $85.4 million for the nine months ended September 30, 2003. Gross profit from net product sales by business segment for the three and nine months ended September 30, 2004 and 2003, respectively, are as follows:

(in thousands)	Three Months ended September 30, 2004	Three Months ended September 30, 2003	% Increase	Nine Months ended September 30, 2004	Nine Months ended September 30, 2003 (restated)	% Increase
Consumer products	$ 24,030	$ 20,171	19%	$ 69,388	$ 62,522	11%
Professional diagnostic products	12,312	9,046	37%	36,026	22,842	58%
Total gross profit from net product sales	$ 36,342	$ 29,217	25%	$ 105,414	$ 85,364	24%

A portion of the increase in gross profit from our consumer product sales, comparing the three and nine months ended September 30, 2004 to the same periods in 2003, resulted from our acquisition of Abbott's Fact plus line of consumer diagnostic pregnancy tests in September 2003. For the three and nine months ended September 30, 2004, the Fact plus product line generated gross profit of $1.4 million and $4.2 million, respectively. Organic growth, primarily as a result of the launch of our Clearblue Easy Digital pregnancy and ovulation tests and the commencement of our supply of the digital and visual versions of Pfizer's e.p.t pregnancy tests, also contributed to the increase in our gross profit from our consumer product sales. Such increases were offset by declining profits from our nutritional supplements business. Gross profit from our nutritional supplements business principally the private label business, declined by $1.5 million and $4.0 million, comparing the three and nine months ended September 30, 2004 to the three and nine months ended September 30, 2003, respectively, while sales of nutritional supplements increased. We expect gross profit from our consumer product sales to increase in the remainder of 2004, as we continue to supply Pfizer's digital and visual e.p.t pregnancy tests.

Gross margin from our consumer product sales was 38% and 39% for the three and nine months ended September 30, 2004, respectively, compared to 42% and 44% for the three and nine months ended September 30, 2003, respectively. The restructuring charge recorded in the third quarter of 2004, as discussed above, had the effect of reducing gross margin from our consumer product sales by 276 and 98 basis points for the three and nine months ended September 30, 2004, respectively. The movements in foreign currencies, comparing the three and nine months ended September 30, 2004 to the three and nine months ended September 30, 2003, negatively impacted the gross margin by 381 and 296 basis points, respectively, for our consumer products manufactured at our European subsidiaries and sold in U.S. Dollars. Additionally, our nutritional supplements business, principally the private label business, suffered margin erosion due to pricing competition. For the three and nine months ended September 30, 2004, as compared to the same periods in 2003, the margin erosion of the nutritional supplements business affected our consumer products gross margin by 270 and 290 basis points, respectively. The negative impact of foreign currency movements and margin erosion of our nutritional supplements business was offset in part by the sales of our Clearblue Easy Digital pregnancy test, which has been generating a higher margin as compared to the average margins of our other consumer products.

The increase in gross profit from our professional diagnostic product sales, comparing the three and nine months ended September 30, 2004 to the same periods in 2003, primarily resulted from our acquisitions of the Abbott TestPack, Abbott TestPack plus and Signify product lines from Abbott and ABI. The Abbott professional diagnostic products generated $2.8 million and $9.8 million in gross profit for the three and nine months ended September 30, 2004, respectively. The ABI products incrementally generated $0.6 million and $4.3 million of gross profit for the three and nine months ended September 30, 2004, respectively, as compared to the same periods in 2003.

Gross margin from our professional diagnostic product sales was 38% and 39% for the three and nine months ended September 30, 2004, respectively, compared to 42% for both the three and nine months ended September 30, 2003. The decline in gross margin of our professional diagnostic products primarily resulted from the ABI products which on average have been generating lower margins than our other professional products.

Research and Development Expense. Research and development expense increased by $1.5 million, or 22%, to $7.9 million for the three months ended September 30, 2004 from $6.4 million for the three months ended September 30, 2003. Research and development expense increased by $6.2 million, or 36%, to $23.3 million for the nine months ended September 30, 2004 from $17.1 million for the nine months ended September 30, 2003. A significant portion of our research and development spending occurs at our facilities in the United Kingdom. As a result, the weak U.S. Dollar against the Pounds Sterling causes an increase in the dollar value of research and development expense at translation. Adjusted for the unfavorable impact of currency translation, research and development expense in the three and nine months ended September 30, 2004 increased by approximately $0.9 million, or 13%, and $4.3 million, or 25%, respectively, compared to the same periods in 2003. Our acquisitions of Ostex and ABI, primarily in the field of osteoporosis and professional diagnostic testing, contributed $0.4 million and $1.4 million of the currency adjusted increase in research and development expense, comparing the three and nine months ended September 30, 2004 to the same periods in 2003, respectively. The remaining currency adjusted increase in research and development expense of $0.5 million and $2.9 million, comparing the three and nine months ended September 30, 2004 to the same periods in 2003, respectively, primarily related to our continued significant investment in the development of products in the field of cardiology, including a pro-thrombin test, scheduled for launch in the first half of 2005, and a congestive heart failure product which remains on track for launch in late 2005. For factors that may impact our ability to meet our expectations to launch these products, see "Certain Factors Affecting Future Results."

Sales and Marketing Expense. Sales and marketing expense increased by $1.5 million, or 11%, to $14.8 million for the three months ended September 30, 2004 from $13.3 million for the three months ended September 30, 2003. Sales and marketing expense increased by $5.9 million, or 16%, to $42.8 million for the nine months ended September 30, 2004 from $36.9 million for the nine months ended September 30, 2003. A significant portion of our sales and marketing spending occurs at our European subsidiaries. Accordingly, and as a result of the continued weak U.S. Dollar, the currency adjusted increase in sales and marketing expense, comparing the three and nine months ended September 30, 2004 to the same periods in 2003, was $0.9 million and $4.1 million, respectively. The currency adjusted increase in sales and marketing expense primarily resulted from our various acquisitions since June 2003, particularly as a result of amortization of acquired customer related intangible assets.

Sales and marketing expense as a percentage of net product sales decreased to 16% for the three and nine months ended September 30, 2004, respectively, from 18% and 19% for the three and nine months ended September 30, 2003, respectively. These percentage decreases resulted primarily from the shift to our professional diagnostics business which generally incur lower sales and marketing expense as a percentage of sales compared to our consumer products business. In addition, marketing synergies realized due to our integration of the Fact plus product line acquired from Abbott Laboratories with only nominal increases in consumer sales and marketing infrastructure accounted for approximately 50 basis points of the reductions in sales and marketing expense as a percentage of sales for each of the three and nine month periods ended September 30, 2004.

General and Administrative Expense. General and administrative expense increased by $5.5 million, or 71%, to $13.1 million for the three months ended September 30, 2004 from $7.6 million for the three months ended September 30, 2003. General and administrative expense increased by $14.5 million, or 60%, to $38.5 million for the nine months ended September 30, 2004 from $24.0 million for the nine months ended September 30, 2003. The impact of foreign exchange translation resulted in an increase in general and administrative expense of $0.6 and $1.3 million for the three and nine months ended September 30, 2004, as compared to the same periods in 2003, respectively. Included in general and administrative expense for the nine months ended September 30, 2004 was the establishment of a specific reserve for a doubtful accounts receivable balance of $1.4 million. Additionally, legal expenses increased $2.5 million and $2.8 million, comparing the three and nine months ended September 30, 2004 to the same periods in 2003, respectively. Further, our acquisitions since June 2003 contributed an additional $1.7 million and $3.2 million to general and administrative expense during the three and nine months ended September 30, 2004, compared to the same periods in 2003, respectively. The remaining increase in general and administrative expenses resulted from the organic growth of our business.

General and administrative expense as a percentage of net product sales was 13% and 14% for the three and nine months ended September 30, 2004, respectively, compared to 11% and 12% for the three and nine months ended September 30, 2003, respectively.

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 and the change in market value of our interest rate swap agreement which did not qualify as a hedge for accounting purposes. Interest expense increased by $2.4 million, or 98%, to $4.8 million for the three months ended September 30, 2004 from $2.4 million for the three months ended September 30, 2003. Interest expense increased by $10.5 million, or 155%, to $17.2 million for the nine months ended September 30, 2004 from $6.7 million for the nine months ended September 30, 2003. In the nine months ended September 30, 2004, we recorded a charge of $3.8 million representing the write-off of 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 $2.4 million and $6.6 million, comparing the three and nine months ended September 30, 2004 to the same periods in 2003, respectively. Such increase was primarily due to a higher average outstanding debt balance which was $188.1 million during the nine months ended September 30, 2004, compared to $140.5 million during the nine months ended September 30, 2003, primarily as a result of the borrowings to finance the acquisitions of ABI and the product lines from Abbott in the second half of 2003. Additionally, the 8.75% interest rate on the $150.0 million Bonds increased our average interest expense to 8.4% as of September 30, 2004, compared to 6.4% as of September 30, 2003. 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 facilities.

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:

	Three Months ended September 30,		Nine Months ended September 30,	
(in thousands)	**2004**	**2003**	**2004**	**2003**
Interest income	$ 234	$ 232	$ 806	$ 801
Foreign exchange gains and (losses), net	166	(296)	15	202
Other	779	431	834	5,384
Total other income, net	$ 1,179	$ 367	$ 1,655	$ 6,387

Included in other income, net for the three and nine months ended September 30, 2004 is $0.5 million of royalties received attributable to periods prior to 2004 associated with a license arrangement that had historically been underpaid. Included in other income, net, for the nine months ended September 30, 2003 is $1.2 million of past royalties received as part of a patent infringement settlement and a one-time gain of $3.8 million recorded in connection with an agreement with Unilever

Plc (the seller of the Unipath business) which resolved certain issues that arose out of our acquisition of the Unipath business.

Income Tax Provision. During the three and nine months ended September 30, 2004, we recorded an income tax provision of $1.2 million and $3.2 million, respectively, compared to $0.8 million and $3.2 million for the three and nine months ended September 30, 2003, respectively. The 2004 provision recorded relates to foreign and state income taxes and the recognition of a U.S. deferred tax liability related to temporary differences between the book and tax bases of goodwill and certain intangible assets with indefinite lives created as part of the acquisition of the Abbott business. Although we incurred a pre-tax loss in 2004, certain domestic and foreign subsidiaries realized pre-tax income. These subsidiaries recorded a tax provision based on the applicable statutory income tax rates. The effective tax rate was (113)% and (32)% for the three and nine months ended September 30, 2004, respectively, compared to 38% and 27% for the three and nine months ended September 30, 2003, respectively. The significant change in the effective tax rates is primarily due to our inability to benefit current losses in most tax jurisdictions.

Net (Loss) Income. We incurred a net loss for the three and nine months ended September 30, 2004 of $2.3 million and $13.0 million, respectively, while for the three and nine months ended September 30, 2003, we generated net income of $1.3 million and $8.4 million, respectively. After taking into account charges for redemption premium and amortization of a beneficial conversion feature related to our Series A redeemable convertible preferred stock, we had a net loss available to common stockholders of $2.3 million, or $0.11 per basic and diluted common share, for the three months ended September 30, 2004, compared to basic and diluted income available to common stockholders of $1.1 million, or $0.07 and $0.06 per basic and diluted common share, respectively, for the three months ended September 30, 2003. We had a net loss available to common stockholders of $13.0 million, or $0.69 per basic and diluted common share, for the nine months ended September 30, 2004, compared to basic and diluted income available to common stockholders of $8.0 million and $8.1 million, or $0.54 and $0.48 per basic and diluted common share, respectively, for the nine months ended September 30, 2003. The loss for the three and nine months ended September 30, 2004 and the income recorded in the same periods in 2003 resulted primarily from the various factors as discussed above. See note 5 of our condensed consolidated financial statements included elsewhere in this quarterly report on Form 10-Q for the calculation of earnings 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 and credit facilities will be adequate to fund our operations, including our outstanding debt and other commitments, as discussed below, for the next 12 months. In the long-run, we expect to fund our working capital needs and other commitments through our operating cash flow, primarily as we expect to grow our business through new product introduction and market share through our strong intellectual property position. Our current cost savings initiatives, including our plan to move certain of our manufacturing to China and consolidate our U.S. packaging and distribution facilities, should help fund our working capital needs and commitments as well, both in the short- and long-term. We also expect to rely on our credit facilities to fund a portion of our capital needs and other commitments.

Our funding plans for our working capital needs and other commitments may be adversely impacted by unexpected costs associated with prosecuting and defending our existing lawsuits and/or unforeseen lawsuits against us, integrating the operations of ABI and the product lines 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 September 30, 2004, we had cash and cash equivalents of $18.9 million, a $5.7 million decrease, or 23%, from December 31, 2003. Since our split-off from our former parent company and its merger transaction with Johnson & Johnson in November 2001, we have funded our business through operating cash flows, proceeds from borrowings and the issuance of equity securities. During the nine months ended September 30, 2004, we generated cash of $3.4 million from our operating activities, which resulted from income, adjusted for non-cash items, of $10.6 million and a net working capital increase, excluding the change in cash balance, of $7.1 million. The increase in working capital consists principally of a $9.3 million increase in inventories and a $1.7 million increase in accounts receivable. Our non-equity financing activities, primarily the issuance of the Bonds in February 2004, net of repayments of borrowings under our primary senior credit facility and certain subordinated notes and bond origination costs, provided us with cash of $18.4 million during the nine months ended September 30, 2004. In addition, we received $1.4 million in proceeds from the exercises of common stock options during the nine months ended September 30, 2004.

During the nine months ended September 30, 2004, we used cash of $28.6 million for investing activities which consisted of $12.3 million paid for transaction costs associated with previously acquired businesses and the recent acquisitions of Viva Diagnostika and Advantage Diagnostics Corporation, or ADC, and for the acquisition of certain intellectual property, $15.2 million in capital expenditures, net of proceeds from sales of equipment and an increase in other non-current assets of $1.1 million. Fluctuations in foreign currencies negatively impacted our cash balance by $0.4 million during the nine months ended September 30, 2004.

Investing Activities

During the nine months ended September 30, 2004, we incurred $15.2 million in capital expenditures, net of proceeds from sales of equipment. We incurred capital expenditures of approximately $0.9 million for the preparation of our facilities for the manufacture of the visual version of Pfizer's e.p.t pregnancy test which we began to sell to Pfizer in June 2004, $3.0 million in connection with the cardiology products that we expect to launch beginning in the first half of 2005, and $1.0 million for new tools related to the manufacture of a new format of our drugs of abuse test. We also continued to make significant investment in laboratory instrument systems that we placed with our customers in connection with our roll out of certain of our professional diagnostic products, which amounted to $2.4 million for the nine months ended September 30, 2004. Other miscellaneous capital expenditures during the nine months ended September 30, 2004 included: (i) approximately $1.5 in machinery in connection with the transition of the manufacturing of the Abbott products from Abbott, (ii) $0.9 million in computer software in connection with the implementation of the SAP system in our U.S. facilities, (iii) $1.6 million in leasehold improvements in connection with our initiative to consolidate our U.S. distribution facility. The remaining capital expenditures during the nine months ended September 30, 2004 were incurred for the purchase of additional equipment to support our organic growth and various research and development activities.

On June 16, 2004, we acquired ADC, a closely held lateral flow diagnostic company that specializes in rapid test development and component manufacturing. The purchase price of ADC consisted of $2.4 million in cash and $0.2 million in assumed debt. The terms of the merger agreement also provide for $1.5 million of contingent consideration payable to the ADC shareholders upon the successful completion of a new product under development by December 31, 2005. We believe that the acquisition of ADC and the addition of ADC's chief scientist to our existing staff will deepen our scientific research management and expand our intellectual property capabilities.

On June 2, 2004, we acquired Viva, a closely held distributor of professional diagnostic products to the German marketplace. The purchase price of Viva consisted of $2.6 million in cash, 155,000 shares of our common stock with an aggregate fair value of $3.0 million and approximately $0.3 million in assumed debt. We believe that Viva, with its established German distribution network, will provide us with expanded distribution channel for our professional diagnostic products, as well as for our cardiac products in development.

Financing Activities

On February 10, 2004, we completed the sale of $150.0 million of 8.75% Bonds due 2012 in a private placement to qualified institutional buyers. Net proceeds from this offering amounted to $145.9 million, which was net of underwriters' commissions of $4.1 million. Of the net proceeds, we used $125.3 million to repay all of our outstanding indebtedness and related financing fees under our primary senior credit facility and $9.2 million to prepay our outstanding 9% subordinated promissory notes and related prepayment penalties, as discussed below. The remaining $11.4 million of proceeds was used for Bond offering expenses and general corporate purposes.

The 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 will be payable semi-annually in arrears on each February 15 and August 15, commencing on August 15, 2004. As of September 30, 2004, accrued interest related to the Bonds amounted to $1.6 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, which, as of September 30, 2004, excluded our subsidiary Inverness Medical Nutritionals Group, or IMN. On October 20, 2004, IMN was designated as an additional guarantor under the Bonds. 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. Prior to the repayment of all borrowings under this senior credit facility using the proceeds from our Bond offering in February 2004, as discussed above, we had obtained term loans aggregating $84.9 million and drawn upon the revolving lines of credit in the aggregate amount of $39.9 million. At September 30, 2004, we had $9.7 million of borrowings outstanding under the revolving lines of credit. In October 2004, we borrowed an additional $15.2 million under this senior credit facility to refinance the outstanding borrowings under IMN's senior credit facility and bonds payable, as discussed below.

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, excluding IMN's. As of September 30, 2004, the applicable interest rate under the revolving lines of credit, including the applicable margin, was 5.49%.

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 IMN through October 2004, and Orgenics Ltd., our Israeli subsidiary, and Unipath Scandinavia AB, our Swedish subsidiary, and the stock of IMN, 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, 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, as amended. With the repayment of the outstanding borrowings under IMN's senior credit facility and bonds payable in October 2004, IMN became a credit party under our senior credit facility and was designated a restricted subsidiary and guarantor under the Bonds.

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. 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 starting 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.

On September 20, 2002, also in connection with the financing of the Wampole acquisition, we sold 9% subordinated promissory notes in an aggregate principal amount of $9.0 million and 3% subordinated convertible promissory notes in an aggregate principal amount of $6.0 million to private investors for an aggregate purchase price of $15.0 million. The 9% subordinated notes and 3% convertible notes accrue interest on the outstanding principal amount at 9% and 3% per annum, respectively, which is payable quarterly in arrears on the first day of each calendar quarter starting October 1, 2002.

In February 2004, we prepaid the outstanding balance of the 9% subordinated notes, or $9.0 million, and a consequential prepayment penalty of $180,000 with the proceeds from the Bond issuance, as discussed above.

The 3% subordinated notes mature on September 20, 2008, subject to acceleration in certain circumstances. If we repay the 3% convertible notes, we may do so 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. At any time prior to the maturity date, the holders of the 3% convertible notes have the option to convert all of their outstanding principal amounts and unpaid interest into shares of our common stock at a conversion price equal to $17.45. Additionally, the outstanding principal amount and unpaid interest on the 3% convertible notes will automatically convert into common stock at a conversion price equal to $17.45 if, at any time after September 20, 2004, the average closing price of our common stock in any consecutive thirty day period is greater than $22.67. An entity controlled by our chief executive officer purchased 3% convertible notes in the aggregate principal amount of $3.0 million.

As of September 30, 2004, our subsidiary IMN had a total outstanding debt balance of $15.5 million, of which $11.8 million represented borrowings under a credit agreement with its senior lender and $3.7 million related to bonds payable and capital leases. In October 2004, using proceeds from borrowings under our senior credit facility, we repaid all outstanding borrowings under IMN's senior credit facility which totaled $14.2 million as of the date of repayment (including a $0.2 million prepayment penalty) and $1.5 million of bonds payable. IMN's other capital leases mature on various dates through July 2008.

In January 2004, all of our then outstanding Series A redeemable convertible preferred stock, or 208,060 shares, were converted at our option into 416,120 shares of our common stock.

Income Taxes

As of December 31, 2003, we had approximately $73.8 million and $20.6 million of domestic and foreign net operating loss carryforwards, respectively, which either expire on various dates through 2023 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 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%. In addition, the domestic operating loss carryforward amount at December 31, 2003 included approximately $48.1 million of pre-acquisition losses at IMN and Ostex. These pre-acquisition losses are subject to the IRS Code Section 382 limitation. Section 382 imposes an annual limitation on the use of these losses to an amount equal to the value of the acquired company multiplied by the long term tax exempt rate. We have recorded a valuation allowance against a portion of the deferred tax assets related to our net operating losses and certain of our other deferred tax assets to reflect uncertainties that might affect the realization of such deferred tax assets, as these assets can only be realized via profitable operations.

Off-Balance Sheet Arrangements

We had no material off-balance sheet arrangements as of September 30, 2004.

Contractual Obligations

The following table summarizes our principal contractual obligations as of September 30, 2004 that have changed significantly since December 31, 2003 and the effects such obligations are expected to have on our liquidity and cash flow in future periods. Contractual obligations that were presented in our annual report on Form 10-K/A for the year ended December 31, 2003 but omitted in the table below represent those that have not changed significantly since December 31, 2003.

	Payments Due by Period				
Contractual Obligations	**Total**	**Remainder of 2004**	**2005-2006**	**2007-2008**	**Thereafter**
			(in thousands)		
Long-term debt obligations(1)	$ 198,974	$ 34	$ 24	$ 48,916	$ 150,000
Purchase obligations capital expenditure(2)	6,053	6,053			
Purchase obligations other (3)	35,040	35,040			

(1) The total amount and scheduled payments of long-term debt obligations changed significantly since December 31, 2003 as a result of the $150.0 million Bond issuance in February 2004 and borrowings under our senior credit facility. Debt maturities reflect the refinancing of the IMN senior credit facility and bonds payable in October 2004 with borrowings under our senior credit facility.

(2) Purchase obligations of capital expenditure increased by $4.0 million, as compared to the commitments at December 31, 2003. See discussion related to capital expenditure in the above section titled "Liquidity and Capital Resources Investing Activities."

(3) Other purchase obligations relate to inventory purchases and other operating expense commitments. Other purchase obligations increased by $21.5 million, as compared to the commitments at December 31, 2003, which primarily resulted from increased inventory purchase commitments in anticipation of sales increases in the remainder of 2004 and the manufacturing transition of certain of the acquired Abbott products to our facilities.

Critical Accounting Policies

The consolidated financial statements included elsewhere in this quarterly report on Form 10-Q are prepared in accordance with 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, 2003 included in our annual report on Form 10-K/A filed on February 11, 2005, 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 do not enter into arrangements with multiple element deliverables. 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 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 recognize revenue on sales of the TestPack products when title transfers 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

Sales arrangements with customers for our consumer products generally 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. 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 approximately $13.7 million and $40.3 million for the three and nine months ended September 30, 2004, respectively, compared to $11.0 million and $32.2 million for the three and nine months ended September 30, 2003, respectively, which have been recorded against product sales to derive our net product sales.

Similarly, our management must make estimates regarding uncollectible accounts receivable balances. When evaluating the adequacy of the allowance for doubtful accounts, management analyzes specific accounts receivable balances, historical bad debts, customer concentrations, customer credit-worthiness, current economic trends and changes in our customer payment terms and patterns. Our accounts receivable balance was $57.7 million and $55.4 million, net of allowances for doubtful accounts of $2.2 million and $0.8 million, as of September 30, 2004 and December 31, 2003, respectively. The significant increase in the allowance for doubtful accounts from December 31, 2003 to September 30, 2004 primarily resulted from the establishment of a specific reserve for a doubtful accounts receivable balance of $1.4 million associated with a private label customer that failed to perform under the terms of our agreement during the second quarter of 2004 and is now the subject of legal action commenced in July 2004.

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 and manufacturing lead times. 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 $57.7 million and $47.4 million, net of a provision for excess and obsolete inventory of $4.1 million and $2.1 million, as of September 30, 2004 and December 31, 2003, respectively.

Valuation of Goodwill and Other Long-Lived and Intangible Assets

Our long-lived assets include (1) property, plant and equipment, (2) goodwill and (3) other intangible assets. As of September 30, 2004, the balances of property, plant and equipment, goodwill and other intangible assets, net of accumulated depreciation and amortization, were $62.6 million, $222.4 million and $120.0 million, respectively.

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

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

Valuation of Goodwill

We have goodwill balances related to our consumer diagnostics and professional diagnostics reporting units, which amounted to $86.9 million and $135.5 million, respectively, as of September 30, 2004. As of December 31, 2003, 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 December 31, 2003, which could lead to significant impairment charges of goodwill in the future. No events or circumstances have occurred since our review as of December 31, 2003, that would require us to reassess whether the carrying values of our goodwill have been impaired.

Valuation of Other Long-Lived Tangible and Intangible Assets

Factors we generally consider important which could trigger an impairment review on the carrying value of other long-lived tangible and intangible assets include the following: (1) significant underperformance relative to expected historical or projected future operating results; (2) significant changes in the manner of our use of acquired assets or the strategy for our overall business; (3) underutilization of our tangible assets; (4) discontinuance of product lines by ourselves or our customers; (5) significant negative industry or economic trends; (6) significant decline in our stock price for a sustained period; (7) significant decline in our market capitalization relative to net book value; and (8) goodwill impairment identified during an impairment review under SFAS No. 142. Although we believe that the carrying value of our long-lived tangible and intangible assets was realizable as of September 30, 2004, 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 $69.4 million as of December 31, 2003 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.

Legal Contingencies

In the section of our annual report on Form 10-K/A for the year ended December 31, 2003 titled "Item 3. Legal Proceedings" and 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.

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, 28 and 60 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 October 20, 2004, we had approximately $203.2 million in aggregate principal indebtedness outstanding, of which $24.9 million is secured indebtedness, and $25.1 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 the senior subordinated notes, we may incur additional indebtedness. During the year ended December 31, 2003 and the nine months ended September 30, 2004, we recorded $9.7 million and $17.2 million, respectively, of interest expense related to our indebtedness, which included $1.0 million and $4.0 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, ABI, and the assets related to the rapid diagnostics product lines that we acquired from Abbott Laboratories, or the Abbott rapid diagnostics product lines.

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

As of October 20, 2004, we had approximately $24.9 million of indebtedness outstanding under our senior credit facility and approximately $25.1 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 3% convertible notes, 10% subordinated notes and, if the lenders accelerate the debt under our senior credit facility, the indenture, 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, and in particular our acquisitions of ABI and the Abbott rapid diagnostics product lines, may not be profitable, and the integration of these businesses or product lines may be costly and difficult and may cause disruption of our business.

Since we commenced activities in November 2001, we have acquired and attempted to integrate 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, and Ostex. On August 27, 2003, we acquired ABI, and on September 30, 2003, we acquired the Abbott rapid diagnostics product lines. We have also made smaller acquisitions such as our recent acquisitions of Viva Diagnostika and Advantage Diagnostics Corporation. 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 product lines into our existing businesses. However, the successful integration of independent companies or product lines 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 Ostex and ABI and the product lines acquired from Abbott Laboratories, 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 company, product line or assets that we have acquired may not be greater than or equal to their purchase prices.

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;
- the inability to achieve anticipated synergies, cost savings or growth opportunities;
- potential loss of key employees, particularly those of the acquired business;
- 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 and the Abbott rapid diagnostics product lines, we have recorded 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 our Clearblue products and some of our 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, 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.

We currently produce most of our consumer products in our manufacturing facilities located in New Jersey, San Diego, Bedford, England and Galway, Ireland and some of our professional diagnostic tests in our manufacturing facilities located in Bedford, England, San Diego and Yavne, Israel. Our production 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 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 Abbott rapid diagnostics product lines 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 (such as SARS), 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.

Sales of our new digital pregnancy tests, including a digital version of Pfizer's e.p.t pregnancy test, may dilute sales of our other consumer pregnancy test products or the non-digital e.p.t pregnancy test, which we also manufacture for Pfizer, and, accordingly, these sales may not increase our overall revenues or profitability.

In the second quarter of 2003, we shipped the first orders for our new digital pregnancy test, Clearblue Easy Digital, which is the first consumer pregnancy test on the market to display test results in words. We also entered into a supply agreement with Pfizer pursuant to which we began in December 2003 supplying Pfizer with a digital version of its e.p.t pregnancy tests on a non-exclusive basis. Instead of interpreting colored lines for a result, the digital display will spell out "Pregnant" or "Not Pregnant." We cannot assure you that sales of these new products will not dilute sales of our other consumer pregnancy test products or the non-digital e.p.t pregnancy test, which we will manufacture for Pfizer until June 2009. Accordingly, there is no assurance that these new products will increase our overall revenues or profitability.

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.

While we currently expect to submit a pro-thrombin test for FDA approval in early 2005 and to launch a congestive heart failure product in late 2005 and have recently announced several new infectious disease products (including a high sensitivity, CLIA waived strep throat test and tests for D-Dimer, Fecal Occult Blood and rapid influenza A & B tests), the factors listed above, as well as manufacturing or distribution problems, or other factors beyond our control, could delay these 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 these 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.

Consistent with our announced plans, our centralized U.S. consumer products packaging and distribution facility recently commenced operations, and we have 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.

If we fail to meet strict regulatory requirements, we could be required to pay fines 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 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. These 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 brand name 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 until the year 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. Though we did experience a slight increase in sales during 2002, the overall trend of declining sales for these products continued in 2003. 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.

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. Our material pending legal proceedings are:

- a counterclaim by Princeton BioMeditech Corporation, or PBM, against us in a patent infringement suit maintained by our subsidiaries, Inverness Medical Switzerland GmbH and Unipath Diagnostics, Inc., against PBM et. al. in which PBM alleges that we have breached various obligations to PBM arising out of its joint venture with us; and

- a suit brought by Quidel Corporation alleging that we are infringing U.S. Patent No. 4,943,522 and seeking a declaratory finding that Quidel does not infringe certain of our patents and certain other patents owned by co-defendant Armkel LLC and that the patents are invalid and/or unenforceable.

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 year ended December 31, 2003 and the nine months ended September 30, 2004, 69% and 66% of our net product sales, respectively, were derived from our consumer products business. Our consumer products 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 high, especially in our private label nutritional supplements business. 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