INVERNESS MEDICAL INNOVATIONS INC
Form 10-Q
November 09, 2005

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(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, 2005**

OR

o **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from to**

COMMISSION FILE NUMBER 001-16789

INVERNESS MEDICAL INNOVATIONS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

DELAWARE	**04-3565120**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

51 SAWYER ROAD, SUITE 200

WALTHAM, MASSACHUSETTS 02453

(Address of principal executive offices)

(781) 647-3900

(Registrant s Telephone Number, Including Area Code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ý **No** o

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

Yes ý **No** o

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

Yes o **No** ý

The number of shares outstanding of the registrant s common stock as of November 4, 2005 was 27,371,965.

INVERNESS MEDICAL INNOVATIONS, INC.

FORM 10-Q

For the Quarterly Period Ended September 30, 2005

This quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Readers can identify these statements by forward-looking words such as may, could, should, would, intend, will, expect, anticipate, believe, estimate, continue or similar words. There are important factors that could cause actual results of Inverness Medical Innovations, Inc. and its subsidiaries to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the risk factors detailed in this quarterly report on Form 10-Q and other risk factors identified from time to time in our periodic filings with the Securities and Exchange Commission. Readers should carefully review the factors discussed in the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations Certain Factors Affecting Future Results and Special Statement Regarding Forward-Looking Statements beginning on pages 28 and 53, 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.

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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,	
	2005	**2004**	**2005**	**2004**
Net product sales	$ 101,808	$ 93,870	$ 289,280	$ 269,624
License revenue	4,486	2,807	11,205	7,304
Net revenues	106,294	96,677	300,485	276,928
Cost of sales (Note 8)	66,659	58,961	193,948	166,687
Gross profit	39,635	37,716	106,537	110,241
Operating expenses:				
Research and development	7,996	7,850	20,587	23,265
Sales and marketing	17,660	14,824	52,356	42,836
General and administrative	14,401	13,053	44,758	38,510
Total operating expenses	40,057	35,727	117,701	104,611
Operating (loss) income	(422)	1,989	(11,164)	5,630
Interest expense, including amortization of discounts and write-off of deferred financing costs (Note 10)	(5,457)	(4,846)	(15,430)	(17,157)
Other income, net (Note 13)	295	1,179	20,079	1,655
Loss before income taxes	(5,584)	(1,678)	(6,515)	(9,872)
Income tax provision	988	1,202	5,355	3,124
Net loss	$ (6,572)	$ (2,880)	$ (11,870)	$ (12,996)
Net loss available to common stockholders basic and diluted (Note 5)	$ (6,572)	$ (2,880)	$ (11,870)	$ (13,745)
Net loss per common share basic and diluted (Note 5)	$ (0.25)	$ (0.14)	$ (0.51)	$ (0.69)
Weighted average shares basic and diluted (Note 5)	25,951	20,296	23,358	19,813

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, 2005	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 29,973	$ 16,756
Accounts receivable, net of allowances of $8,880 at September 30, 2005 and $9,359 at December 31, 2004	72,885	61,347
Inventories	72,967	61,234
Deferred tax assets	2,961	2,819
Prepaid expenses and other current assets	13,754	9,601
Total current assets	192,540	151,757
Property, plant and equipment, net	71,722	66,780
Goodwill	318,122	221,155
Other intangible assets with indefinite lives	72,588	50,542
Core technology and patents, net	66,887	40,327
Other intangible assets, net	53,558	27,680
Deferred financing costs, net, and other non-current assets	12,823	9,156
Deferred tax assets	14,380	872
Total assets	$ 802,620	$ 568,269
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 2,391	$ 88
Current portion of capital lease obligations	543	467
Accounts payable	39,897	32,345
Accrued expenses and other current liabilities	77,589	56,242
Total current liabilities	120,420	89,142
Long-term liabilities:		
Long-term debt, net of current portion	243,541	189,268
Capital lease obligations, net of current portion	1,122	1,401
Deferred tax liabilities	27,816	12,596
Other long-term liabilities	4,542	4,446
Total long-term liabilities	277,021	207,711
Commitments and contingencies		
Series A redeemable convertible preferred stock, $0.001 par value:		
Authorized 2,667 shares		
Issued 2,527 shares		
Outstanding none		

Stockholders equity:				
Preferred stock, $0.001 par value:				
Authorized 2,333 shares, none issued				
Common stock, $0.001 par value:				
Authorized 50,000 shares				
Issued and outstanding 27,356 shares at September 30, 2005 and 20,711 shares at December 31, 2004		27		21
Additional paid-in capital		513,633		359,582
Notes receivable from stockholders		(14,691)		(14,691)
Accumulated deficit		(102,887)		(91,017)
Accumulated other comprehensive income		9,097		17,521
Total stockholders equity		405,179		271,416
Total liabilities and stockholders equity	$	802,620	$	568,269

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

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(in thousands)

	Nine Months Ended September 30,	
	2005	**2004**
Cash Flows from Operating Activities:		
Net loss	$ (11,870)	$ (12,996)
Adjustments to reconcile net loss 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	1,660	4,380
Noncash gains related to interest rate swap and currency hedge agreements	212	(326)
Noncash stock-based compensation expense	140	
Depreciation and amortization	18,995	17,641
Deferred income taxes	1,915	1,922
Other noncash items	(11)	(70)
Changes in assets and liabilities, net of acquisitions:		
Accounts receivable, net	8,480	(1,717)
Inventories	(4,457)	(9,273)
Prepaid expenses and other current assets	(3,942)	(189)
Accounts payable	3,655	(3,386)
Accrued expenses and other current liabilities	7,969	6,968
Other long-term liabilities	(124)	489
Net cash provided by operating activities	22,622	3,443
Cash Flows from Investing Activities:		
Purchases of property, plant and equipment	(14,662)	(15,403)
Proceeds from sale of property, plant and equipment	172	184
Payments for acquisitions and intellectual property	(139,681)	(12,275)
Increase in other assets	(1,375)	(1,129)
Net cash used in investing activities	(155,546)	(28,623)
Cash Flows from Financing Activities:		
Cash paid for financing costs	(2,648)	(5,333)
Proceeds from issuance of common stock, net of issuance costs	95,956	1,416
Proceeds from issuance of senior subordinated notes		150,000
Net proceeds (repayments) from revolving lines of credit	54,616	(31,099)
Net borrowings (repayments) of notes payable	69	(94,764)
Principal payments of capital lease obligations	(358)	(362)
Net cash provided by financing activities	147,635	19,858
Foreign exchange effect on cash and cash equivalents	(1,494)	(356)
Net increase (decrease) in cash and cash equivalents	13,217	(5,678)
Cash and cash equivalents, beginning of period	16,756	24,622
Cash and cash equivalents, end of period	$ 29,973	$ 18,944
Supplemental Disclosure of Noncash Activities:		
Dividends, redemption interest and amortization of beneficial conversion feature related to preferred stock	$	$ 749
Fair value of stock issued for acquisitions and intellectual property	$ 57,962	$ 3,002
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, 2004 included information and footnotes necessary for such presentation and were included in our annual report on Form 10-K/A, Amendment No. 1, filed with the Securities and Exchange Commission (SEC) on August 26, 2005. These unaudited consolidated financial statements should be read in conjunction with our audited consolidated financial statements and notes thereto for the year ended December 31, 2004.

(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, 2005, 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, 2005	December 31, 2004
Raw materials	$ 29,127	$ 23,434
Work-in-process	17,463	14,956
Finished goods	26,377	22,844
	$ 72,967	$ 61,234

(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 would have been increased to the pro forma amounts indicated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share amounts)	**2005**	**2004**	**2005**	**2004**
Net loss as reported	$ (6,572)	$ (2,880)	$ (11,870)	$ (12,996)
Stock-based employee compensation as reported			140	
Pro forma stock-based employee compensation	(1,853)	(1,563)	(4,825)	(4,368)
Net loss pro forma	$ (8,425)	$ (4,443)	$ (16,555)	$ (17,364)
Loss per share basic and diluted:				
Net loss per share as reported	$ (0.25)	$ (0.14)	$ (0.51)	$ (0.69)
Stock-based employee compensation as reported				
Pro forma stock-based employee compensation	(0.07)	(0.08)	(0.20)	(0.22)
Net loss per share pro forma	$ (0.32)	$ (0.22)	$ (0.71)	$ (0.91)

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,	
	2005	**2004**	**2005**	**2004**
Risk-free interest rate	3.83-3.98%	3.4-3.5%	3.58-4.09%	2.8-4.0%
Expected dividend yield				
Expected lives	5 years	5 years	5 years	5 years
Expected volatility	45%	48%	45%	48%

The weighted average fair value under the Black-Scholes option pricing model of options granted to employees during the three months ended September 30, 2005 and 2004 were $12.46 and $7.22, 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, 2005 and 2004 were $12.04 and $8.72, respectively.

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(5) Earnings Per Share

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

(in thousands, except per share amounts)	Three Months Ended September 30, 2005	2004	Nine Months Ended September 30, 2005	2004
Numerator:				
Net loss	$ (6,572)	$ (2,880)	$ (11,870)	$ (12,996)
Dividends, redemption interest and amortization of beneficial conversion feature related to Series A Preferred Stock				(749)
Net loss available to common stockholders diluted	$ (6,572)	$ (2,880)	$ (11,870)	$ (13,745)
Denominator:				
Denominator for basic loss per share weighted average shares	25,951	20,296	23,358	19,813
Effect of dilutive securities:				
Employee stock options				
Warrants				
Restricted stock and escrow shares				
Convertible promissory notes				
Dilutive potential common shares				
Denominator for dilutive loss per share adjusted weighted average shares and assumed conversions	25,951	20,296	23,358	19,813
Net loss per share basic and diluted	$ (0.25)	$ (0.14)	$ (0.51)	$ (0.69)

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

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.

(6) Comprehensive Income or Loss

Comprehensive income or loss represents net income or loss plus other comprehensive income or loss items. Our other comprehensive income or loss includes primarily foreign currency translation adjustments. For the three and nine months ended September 30, 2005, we generated a comprehensive loss of $8.9 million and $20.3 million, respectively, and for the three and nine months ended September 30, 2004, we generated comprehensive income of $2.6 million and $12.9 million, respectively.

(7) Business Combinations

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

(a) Acquisition of Biostar

On September 30, 2005, we acquired Thermo BioStar, Inc. (BioStar), a leading developer and manufacturer of high-performance, rapid diagnostic tests, including tests for the detection of infectious diseases. The preliminary aggregate purchase price was $53.0 million which consisted of $52.5 million in cash and $0.5 million in estimated direct acquisition costs.

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

		(in thousands)
Accounts receivable	$	5,247
Inventories		2,046
Property, plant and equipment		1,998
Goodwill		32,357
Core technology and intangible assets		15,000
Other assets		795
Accounts payable and accrued expenses		(4,437)
	$	53,006

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

The acquisition of BioStar is accounted for as a purchase under SFAS No. 141, *Business Combinations*. Accordingly, the operating results of BioStar will be included in the accompanying consolidated financial statements since the acquisition date as part of our professional diagnostic products reporting units and business segment. We will make an election under Section 338 of the Internal Revenue Code to treat this acquisition as an asset acquisition for tax purposes. As a result, goodwill generated from this acquisition will be deductible for tax purposes.

(b) Acquisition of IDT

On September 30, 2005, we acquired Innogenetics Diagnostica Y Terapeutica, S.A.U. (IDT), a Spanish distributor of diagnostic products. The preliminary aggregate purchase price was $20.6 million which consisted of $11.8 million in cash, a working capital adjustment payment to be determined and paid during the fourth quarter, estimated to be approximately $8.6 million, and $0.2 million in estimated direct acquisition costs.

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

		(in thousands)
Cash and cash equivalents	$	76
Accounts receivable		10,988
Inventories		562
Property, plant and equipment		771
Goodwill		3,678
Acquired intangibles		7,500
Other assets		188
Deferred tax asset		2,625
Accounts payable and accrued expenses		(3,211)
Deferred tax liability		(2,625)
	$	20,552

The above values for the assets acquired and subsequent amortization and liabilities assumed are based on preliminary management estimates. Final purchase price allocation may differ from the above. Management is also in the process of determining the useful lives of the acquired intangibles as listed above.

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

(c) Acquisition of Determine

On June 30, 2005, we acquired the Determine/DainaScreen assets of Abbott Laboratories rapid diagnostic business (the Determine business). The Determine business produces diagnostic tests that are designed to provide rapid qualitative results for detecting several diseases, including hepatitis, HIV 1/2 and syphilis. The preliminary aggregate purchase price was $58.0 million, which consisted of $56.5 million in cash and $1.5 million in estimated direct acquisition costs.

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

		(in thousands)
Inventories	$	3,412
Property, plant and equipment		1,500
Goodwill		35,282
Acquired intangibles		21,000
Accrued expenses		(3,145)
	$	58,049

The above values for the assets acquired are based on preliminary management estimates due to the timing of the acquisition. Final purchase price allocation may differ from the above. Management is also in the process of determining the useful lives of the acquired intangibles as listed above. We estimate the useful lives of the manufacturing know how to be 10 years and customer related intangible asset to be 6 years and included them in other intangible assets, net, in the accompanying consolidated balance sheets.

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

(d) Acquisition of Binax

On March 31, 2005, we acquired Binax, Inc. (Binax), a privately held developer, manufacturer and distributor of rapid

diagnostic products for infectious disease testing, primarily related to the respiratory system. The preliminary aggregate purchase price was $44.7 million which consisted of $9.0 million in cash, 1.4 million shares of our common stock with an aggregate fair value of $35.2 million and $0.5 million in estimated direct acquisition costs. The terms of the acquisition agreement also provide for $11.0 million of contingent cash consideration payable to the Binax shareholders upon the successful completion of certain new product developments during the next five years. This contingent consideration will be accounted for as an increase in the preliminary aggregate purchase price and goodwill if and when the contingency occurs.

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

		(in thousands)
Cash and cash equivalents	$	1,556
Accounts receivable		5,264
Inventories		3,086
Property, plant and equipment		2,421
Goodwill		18,791
Core technology and intangible assets		15,000
Other assets		845
Deferred tax asset.		6,000
Accounts payable and accrued expenses		(2,231)
Deferred tax liability		(6,000)
	$	44,732

The above values for the assets acquired and subsequent amortization and liabilities assumed are based on preliminary management estimates. Final purchase price allocation may differ from the above. Management is also in the process of determining the useful lives of the core technology and intangible assets as listed above. We estimate the useful lives of the core technology to be 15 years and customer related intangible asset to be 7 years and included them in core technology and patents, net, and other intangible assets, net, respectively, in the accompanying consolidated balance sheets.

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

(e) Acquisition of Ischemia

On March 16, 2005, we acquired Ischemia Technologies, Inc. (Ischemia), a privately held, venture-backed company that developed, manufactures and markets the only FDA-cleared *in vitro* diagnostic test targeted on cardiac ischemia. The preliminary aggregate purchase price was $27.3 million, which consisted of 968,000 shares of our common stock with an aggregate fair value of $22.8 million, estimated exit costs of $1.7 million to vacate Ischemia s manufacturing and administrative facilities, which we recorded in accordance with Emerging Issues Task Force (EITF) Issue No. 95-3, *Recognition of Liabilities in Connection with a Purchase Business Combination,* estimated direct acquisition costs of $2.3 million and $0.5 million in assumed debt.

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

		(in thousands)
Cash and cash equivalents	$	115
Accounts receivable		58
Inventories		40
Property, plant and equipment		288
Goodwill		7,701
Patents		19,200
Customer relationships		200
Other assets		99
Deferred tax asset		7,760
Accounts payable and accrued expenses		(377)
Deferred tax liability		(7,760)
	$	27,324

The above values for the assets acquired and subsequent amortization and liabilities assumed are based on preliminary management estimates due to the timing of the acquisition. Final purchase price allocation may differ from the above values. We estimated the useful lives of the patents to be from 6 to 13 years and customer related intangible asset to be 5.5 years and included them in core technology and patents, net, and other intangible assets, net, respectively, in the accompanying consolidated balance sheets.

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

(f) Acquisition of ACS

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

(g) Pro Forma Financial Information

The following table presents selected unaudited financial information of our company, including Binax, Ischemia, the Determine business, BioStar and IDT as if the acquisitions of these businesses had occurred on January 1, 2004. Pro forma results exclude adjustments for ACS as the historical results of this acquisition do not materially affect our results of operations. The pro forma results are derived from the historical financial results of the acquired businesses for all periods presented and are not necessarily indicative of the results that would have occurred had the acquisitions been consumated on January 1, 2004.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share amounts)	**2005**	**2004**	**2005**	**2004**
Pro forma net revenues	$ 116,491	$ 118,751	$ 355,874	$ 341,821
Pro forma net loss	(8,050)	(6,029)	$ (10,516)	(19,260)

Pro forma net loss available to common stockholders basic and diluted	(8,050)	(6,029)	(10,516)	(20,009)
Pro forma net loss per common share basic and diluted (1)	$ (0.30)	$ (0.23)	$ (0.39)	$ (0.77)

(1) Loss per share amounts are computed as described in Note 5.

(h) Restructuring Plans of Acquisitions

In connection with our acquisitions of Ischemia, Ostex International, Inc. (Ostex), IVC Industries, Inc. (now operating as Inverness Medical Nutritionals Group or IMN) and certain entities, businesses and intellectual property of Unilever Plc (the Unipath business), we recorded restructuring costs as part of the respective aggregate purchase prices in accordance with EITF Issue No. 95-3. The following table sets forth the restructuring costs and balances recorded in connection with the restructuring activities of these acquired businesses:

(in thousands)	Balance at December 31, 2004	Costs Added to Purchase Price	Amounts Paid	Other (1)	Balance at September 30, 2005
Ischemia	$	$ 1,725	$ (1,355)	$	$ 370
Ostex	910		(117)		793
IMN	263		(126)		137
Unipath business	1,453			(120)	1,333
Total restructuring costs	$ 2,626	$ 1,725	$ (1,598)	$ (120)	$ 2,633

(1) Represents foreign currency translation adjustment.

In connection with our acquisition of Ischemia in March 2005, we established a restructuring plan whereby we have exited the current facilities of Ischemia in Denver, Colorado, and combined its activities with our existing manufacturing and distribution facilities. Total severance costs associated with involuntarily terminated employees are estimated to be $1.6 million, of which $1.3 million has been paid as of September 30, 2005. We estimated costs to vacate the Ischemia facilities to be approximately $0.1 million, none of which has been paid as of September 30, 2005. We expect to pay the remaining costs during the remainder of 2005. The total number of involuntarily terminated employees was 17, of which all were terminated as of September 30, 2005. Although we believe our plan and estimated exit costs are reasonable, actual spending for exit activities may differ from current estimated exit costs, which might impact the final aggregate purchase price.

As a result of our acquisition of Ostex, we established a restructuring plan whereby we exited the facilities of Ostex in Seattle, Washington, and combined the activities of Ostex with our existing manufacturing and distribution facilities. The total number of employees to be terminated involuntarily under the restructuring plan is 38, of which all were terminated as of September 30, 2005. Total severance costs associated with involuntarily terminated employees are $1.6 million, of which all have been paid as of September 30, 2005. Costs to vacate the Ostex facilities are $0.5 million, of which $0.2 million has been paid as of September 30, 2005. Additionally, the remaining costs to exit operations, primarily facilities lease commitments, are $1.9 million, of which $1.4 million has been paid as of September 30, 2005. Total unpaid exit costs amounted to $0.8 million as of September 30, 2005.

Immediately after the close of the acquisition of IMN, we reorganized the business operations to improve efficiencies and eliminate redundant activities on a company-wide basis. The restructuring affected all cost centers within the organization, but most significantly responsibilities at the sales and executive levels, as such activities were combined with our existing business operations. Also as part of the restructuring plan, we relocated one of IMN s warehouses to a closer proximity of the manufacturing facility to improve efficiency. Of the $1.6 million in total exit costs, which include severance costs of 47 involuntarily terminated employees and costs to vacate the warehouse, $1.5 million has been paid and $0.1 million remains unpaid as of September 30, 2005.

As a result of the acquisition of the Unipath business from Unilever Plc in 2001, we reorganized the operations of the Unipath business for purposes of improving efficiencies and achieving economies of scale on a company-wide basis. Such reorganization affected all major cost centers at the operations in England. Additionally, most business activities of the U.S. division were merged into our existing U.S. businesses. Total exit costs, which primarily related to severance and early retirement obligations of 65 involuntarily terminated employees, were $4.1 million. As of September 30, 2005, $1.3 million, adjusted for foreign exchange effect, in exit costs remained unpaid.

(8) Restructuring Plan

On May 9, 2005, we committed to a plan to cease operations at our facility in Galway, Ireland. During the second quarter ended June 30, 2005, we recorded a $3.5 million restructuring charge, of which $0.9 million related to all expected severance, early retirement, outplacement services and $2.6 million related to impairment of fixed assets relating to this plan of termination. During the third quarter we recorded an additional $0.6 million restructuring charge all related to expected severance, early retirement and outplacement services. The total restructuring charge for the nine months ended September 30, 2005 is $4.1 million, which consisted of $3.5 million charged to cost of goods sold, $0.3 million charged to research and development and $0.3 million charged to general and administrative, was included in our consumer products business segment. The total number of employees to be involuntarily terminated is 109, of which 20 were terminated as of September 30, 2005. As of September 30, 2005, of the $1.5 million related to expected severance, early retirement and outplacement services, $1.2 million remained unpaid. Including the charges recorded in the second and third quarter, we expect the total restructuring charge related to the closure of CDIL to be approximately $6.3 million, with additional charges relating principally to severance and facility closing costs of $1.9 million and $0.3 million, respectively, expected to be recorded in the fourth quarter of 2005 and first quarter of 2006.

(9) Co-Development Arrangement

On February 25, 2005, we entered into a co-development agreement with ITI Scotland Limited (ITI), whereby ITI agreed to provide us with approximately £30 million (or $52.8 million at September 30, 2005) over three years to partially fund research and development programs focused on identifying novel biomarkers and near-patient and home use tests for cardiovascular and other diseases (the programs). We agreed to invest £37.5 million (or $66.1 million at September 30, 2005) in the programs over the next three years. Through our subsidiary, Stirling Medical Innovations Limited (Stirling), we established a new research center in Stirling, Scotland, where we will consolidate many of our existing cardiology programs and ultimately commercialize products arising from the programs. ITI and Stirling will have exclusive rights to the developed technology in their respective fields of use. As of September 30, 2005, we had received approximately $13.7 million in funding from ITI. As qualified expenditures are made under the co-development arrangement, we recognize the fee earned during the period as a reduction of our related expenses, subject to certain limitations. For the three and nine months ended September 30, 2005, we recognized $4.3 million and $13.7 million of reimbursements, respectively, of which $3.8 million and $12.6 million, respectively offset our research and development spending and $0.5 million and $1.1 million, respectively reduced our general, administrative and marketing spending incurred by Stirling, for the three and nine months ended September 30, 2005, respectively. Funds received from ITI in excess of amounts earned are included in accrued expenses and other current liabilities, the balance of which was $4.3 million as of September 30, 2005.

(10) Senior Credit Facility

On June 30, 2005, we amended and restated our existing Senior Credit Facility. The amendment expanded our existing revolving credit facility capacity from $50.0 million to $80.0 million and added a $20.0 million term loan facility. Upon completion of the amendment, we borrowed $58.0 million to finance our acquisition of Determine. In August, 2005, we sold 4,000,000 shares of our common stock to 3 accredited institutional investors in a private placement. Net proceeds from the private placement were approximately $92.8 million. Of this amount, we repaid principal and interest outstanding under Senior Credit Facility of $84.4 million, with the remainder of the net proceeds retained for general corporate purposes. $20 million of the repayment was used to permanently reduce the outstanding term loan balance under the Senior Credit Facility. The repayment of the term loan balance resulted in a non-cash write-off of deferred financing costs of $0.1 million during the third quarter of 2005. On September 29, 2005, we again amended the Senior Credit Facility to increase the total amount of credit available to us under the Senior Credit Facility, which consists of two revolving lines of credit, from $80.0 million to $100.0 million. As of September 30, 2005, $74.0 million of borrowings were outstanding under the lines, with $26.0 million available for future borrowings, subject to continued covenant compliance.

(11) Defined Benefit Pension Plan

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

(in thousands)	Three Months Ended September 30, 2005	2004	Nine Months Ended September 30, 2005	2004
Service cost	$ 64	$ 449	$ 198	$ 1,349
Interest cost	145	51	448	154
Expected return on plan assets	(86)	(45)	(265)	(136)
Realized losses	11	5	33	16
Net periodic benefit costs	$ 134	$ 460	$ 414	$ 1,383

(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 the chief executive officer and members of senior management. Our reportable operating segments are Consumer Diagnostic Products, Vitamins and Nutritional Supplements, Professional Diagnostic Products, and Corporate and Other. Included in the operating loss of Corporate and Other are non-allocable corporate expenditures and expenses related to our research and development activities in the area of cardiology for the three and nine months ended September 30, 2005, the latter of which amounted to $5.0 million, net of the ITI funding of $3.9 million (Note 9) and $11.2 million, net of $12.6 million of the ITI funding, respectively, and $3.9 million and $12.1 million for the three and nine months ended September 30, 2004, respectively. Total assets in the area of cardiology, which are included in Corporate and Other in the tables below, amounted to $50.4 million at September 30, 2005 and $8.6 million at December 31, 2004.

We evaluate performance of our operating segments based on revenue and operating income (loss). Segment information for the three and nine months ended September 30, 2005 and 2004 is as follows:

(in thousands)	Consumer Diagnostic Products	Vitamins and Nutritional Supplements	Professional Diagnostic Products	Corporate and Other	Total
Three Months Ended September 30, 2005					
Net revenue from external customers	$ 40,680	$ 19,395	$ 46,219	$	$ 106,294
Operating income (loss)	6,068	(740)	1,266	(7,016)	(422)
Three Months Ended September 30, 2004					
Net revenue from external customers	46,854	17,409	32,414		96,677
Operating income (loss)	8,961	(833)	737	(6,876)	1,989
Nine Months Ended September 30, 2005					
Net revenue from external customers	126,895	55,234	118,247	109	300,485
Operating income (loss)	19,112	(3,891)	(4,324)	(22,061)	(11,164)
Nine Months Ended September 30, 2004					
Net revenue from external customers	125,094	56,233	95,601		276,928
Operating income (loss)	21,440	(1,430)	6,651	(21,031)	5,630
Assets at September 30, 2005	253,937	54,251	437,726	56,706	802,620
Assets at December 31, 2004	243,001	48,072	264,260	12,936	568,269

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(13) Material Contingencies, Settlements and Other Arrangements

On February 2, 2005, our IMN subsidiary received $8.4 million representing its pro rata share of the net funds which were disbursed in connection with the settlement of class action suits against several raw material suppliers. The class action suits alleged that certain defendants unlawfully agreed to fix prices of certain vitamin products sold in the United States. IMN s recovery represented 7.3% of its approved purchases from the settling parties during the period in which the price fixing was alleged. The $8.4 million is included in other income, net, in the accompanying consolidated statement of operations for the nine months ended September 30, 2005.

On April 6, 2005, we entered into a binding settlement agreement of our pending litigation with Princeton BioMeditech Corporation (PBM) pursuant to which we paid $2.5 million in resolution of all pending litigation with PBM. PBM also received an option to permanently settle certain claims against our subsidiary, Applied Biotech, Inc. (ABI), that are not part of any pending case in exchange for $1.8 million of collaborative research and development funding from us. In connection with the settlement, the parties also entered into an agreement to form a joint venture pursuant to which both companies will make all their sales of existing drugs of abuse products (excluding sales to hospitals) (the New Joint Venture). All products sold by the New Joint Venture will be manufactured by PBM. The New Joint Venture will be owned equally by PBM and us and profits will be distributed in proportion to the trailing 12 month sales of products contributed to the venture. In connection with this settlement arrangement, we recorded a $4.2 million charge which is included in other income, net, in the accompanying consolidated statement of operations for the nine months ended September 30, 2005.

On April 27, 2005, we entered into a settlement agreement with Quidel Corporation (Quidel) terminating all domestic and international intellectual property litigation with them. Under the settlement agreement, we received a net payment of $17.0 million and net future royalties from Quidel at 8.5%, in exchange for a license to all of our current and future patents which embody lateral flow technology for all diagnostic products other than for cardiology testing and for consumer/over-the-counter women s health (except that diagnostics for women s infectious diseases are within the licensed field of use). Quidel and its affiliates are granting a net royalty free cross-license of their current and future patents that embody lateral flow technology to us and all of our affiliates for all applications. The payment of $17.0 million is included in our financial results for the nine months ended September 30, 2005, of which $15.0 million related to periods prior to 2005 and has been included in other income, net and the remainder has been recorded as license revenues.

On June 16, 2005, we entered into a license arrangement with British BioCell International Limited (British BioCell). As part of this agreement, we licensed to them our lateral flow intellectual property for use in certain defined areas not competitive with existing businesses in return for royalties on future sales totaling between 10% and 25% of net revenues, depending on the amounts of revenue earned. As part of the arrangement, we also received an option to acquire 25% of British BioCell s parent company, BBI Holdings, PLC, a UK public company. We valued the option at $2.6 million using the Black-Scholes option pricing model and have included the value received in other income, net, for the nine months ended September 30, 2005. The investment, which is not readily convertible to cash, has been recorded at cost and will be evaluated at least annually for impairment, or more frequently, if events and circumstances indicate.

On September 23, 2005, an arbitrator issued a final award against our IMN subsidiary in favor of Sunlight Distribution, Inc. for damages in the amount of $1.8 million plus interest, fees and costs arising out of a distribution arrangement dated September 1996. We have accrued $2.7 million as of September 30, 2005 to provide for the final award. The corresponding expense was recorded in other income, net, for the nine months ended September 30, 2005.

(14) Recent accounting pronouncements

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

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment,* or SFAS No. 123R. SFAS No. 123R addresses the accounting for transactions in which a company receives employee services in exchange for (a) equity instruments of the company or (b) liabilities that are based on the fair value of the company s equity instruments or that may be settled by the issuance of such equity instruments. It eliminates the ability to account for share-based compensation transactions using APB Opinion No. 25 and

generally requires that such transactions be accounted for using a fair-value-based method. As permitted by the current SFAS No. 123, we have been accounting for share-based compensation to employees using APB Opinion No. 25 s intrinsic value method and, as such, we generally recognize no compensation cost for employee stock options. Under the original guidance of SFAS No. 123R, we were to adopt the statement s provisions for the interim period beginning after June 15, 2005. However, in April 2005, as a result of an action by the Securities and Exchange Commission, companies are allowed to adopt the provisions of SFAS No. 123R at the beginning of their fiscal year that begins after June 15, 2005. Consequently, we will adopt SFAS No. 123R on January 1, 2006. We expect that the requirement to expense stock options and other equity interests that have been or will be granted pursuant to our equity incentive program will significantly increase our operating expenses and result in lower earnings per share. The adoption of SFAS No. 123R will have no impact on our cash flows.

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

In March 2005, the FASB issued FASB Interpretation No. 47 *Accounting for Conditional Asset Retirement Obligations,* which is an interpretation of FASB Statement No. 143, *Accounting for Asset Retirement Obligations.* The interpretation requires a liability for the fair value of a conditional asset retirement obligation be recognized if the fair value of the liability can be reasonably estimated. The interpretation is effective for years ending after December 15, 2005. The interpretation is not expected to have a material impact on our results of operations or financial position.

In May 2005, the FASB issued SFAS No. 154 *Accounting Changes and Error Corrections,* which replaces APB Opinion No. 20 Accounting Changes, and FASB Statement No. 3 *Reporting Accounting Changes in Interim Financial Statements,* and changes the requirements for the accounting for and reporting of a change in accounting principle. SFAS No. 154 requires retrospective application to prior periods financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. SFAS No. 154 shall be effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. Early adoption is permitted for accounting changes and corrections of errors made in fiscal years beginning after the date SFAS No. 154 was issued. At the present time, we do not believe that adoption of SFAS No. 154 will have a material effect on our financial position, results of operations or cash flows.

(15) Guarantor Financial Information

We issued $150.0 million in senior subordinated notes (the Bonds) to qualified institutional buyers in reliance on Rule 144A under the Securities Act of 1933, as amended (the Securities Act), and outside the United States in compliance with Regulation S of the Securities Act. Our payment obligations under the Bonds are currently guaranteed by all of our domestic subsidiaries (the Guarantor Subsidiaries). The guarantee is full and unconditional. Separate financial statements of the Guarantor Subsidiaries are not presented because we have determined that they would not be material to investors in the Bonds. The following supplemental financial information sets forth, on a consolidating basis, the statements of operations and cash flows for the three and nine months ended September 30, 2005 and 2004 and the balance sheets as of September 30, 2005 and December 31, 2004 for our company (the Issuer), the Guarantor Subsidiaries and our other subsidiaries (the Non-Guarantor Subsidiaries). The supplemental financial information reflects our investments and the Guarantor Subsidiaries investments in the Guarantor and Non-Guarantor Subsidiaries using the equity method of accounting.

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

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF OPERATIONS

For the Three Months Ended September 30, 2005

(unaudited)

(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	$ 6,228	$ 57,284	$ 54,280	$ (15,984)	$ 101,808
License revenue		71	4,415		4,486
Net revenues	6,228	57,355	58,695	(15,984)	106,294
Cost of sales	6,315	43,568	31,230	(14,454)	66,659
Gross profit	(87)	13,787	27,465	(1,530)	39,635
Operating expenses:					
Research and development	316	1,570	6,110		7,996
Sales and marketing	712	8,669	8,279		17,660
General and administrative	3,523	3,880	6,998		14,401
Total operating expenses	4,551	14,119	21,387		40,057
Operating (loss) income	(4,638)	(332)	6,078	(1,530)	(422)
Equity in earnings of subsidiaries, net of tax	(1,343)			1,343	
Interest expense, including amortization of discounts and write off of deferred financing costs	(4,082)	(714)	(3,865)	3,204	(5,457)
Other income, net	3,663	138	(241)	(3,265)	295
(Loss) income before income taxes	(6,400)	(908)	1,972	(248)	(5,584)
Income tax provision	172	555	221	40	988
Net (loss) income	$ (6,572)	$ (1,463)	$ 1,751	$ (288)	$ (6,572)

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF OPERATIONS

For the Three Months Ended September 30, 2004

(unaudited)

(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	$ 5,524	$ 56,882	$ 46,444	$ (14,980)	$ 93,870
License revenue		37	2,770		2,807
Net revenues	5,524	56,919	49,214	(14,980)	96,677
Cost of sales	5,212	41,522	25,872	(13,645)	58,961
Gross profit	312	15,397	23,342	(1,335)	37,716
Operating expenses:					
Research and development	81	763	7,006		7,850
Sales and marketing	466	5,744	8,614		14,824
General and administrative	2,324	2,973	7,756		13,053
Total operating expenses	2,871	9,480	23,376		35,727
Operating (loss) income	(2,559)	5,917	(34)	(1,335)	1,989
Equity in earnings of subsidiaries, net of tax	3,135			(3,135)	
Interest expense, including amortization of discounts and write off of deferred financing costs	(4,268)	(462)	(1,230)	1,114	(4,846)
Other income, net	1,151	412	730	(1,114)	1,179
(Loss) income before income taxes	(2,541)	5,867	(534)	(4,470)	(1,678)
Income tax provision	339	437	426		1,202
Net (loss) income	$ (2,880)	$ 5,430	$ (960)	$ (4,470)	$ (2,880)

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF OPERATIONS

For the Nine Months Ended September 30, 2005

(unaudited)

(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	$ 18,204	$ 167,180	$ 148,358	$ (44,462)	$ 289,280
License revenue		197	11,008		11,205
Net revenues	18,204	167,377	159,366	(44,462)	300,485
Cost of sales	18,700	135,932	84,435	(45,119)	193,948
Gross profit	(496)	31,445	74,931	657	106,537
Operating expenses:					
Research and development	1,085	4,187	15,315		20,587
Sales and marketing	1,964	24,781	25,611		52,356
General and administrative	9,972	13,097	21,689		44,758
Total operating expenses	13,021	42,065	62,615		117,701
Operating (loss) income	(13,517)	(10,620)	12,316	657	(11,164)
Equity in earnings of subsidiaries, net of tax	13,310			(13,310)	
Interest expense, including amortization of discounts and write off of deferred financing costs	(12,407)	(1,525)	(6,713)	5,215	(15,430)
Other income, net	1,101	6,278	17,915	(5,215)	20,079
(Loss) income before income taxes	(11,513)	(5,867)	23,518	(12,653)	(6,515)
Income tax provision	357	1,691	3,307		5,355
Net (loss) income	$ (11,870)	$ (7,558)	$ 20,211	$ (12,653)	$ (11,870)

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF OPERATIONS

For the Nine Months Ended September 30, 2004

(unaudited)

(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	$ 15,453	$ 158,769	$ 130,892	$ (35,490)	$ 269,624
License revenue		83	7,221		7,304
Net revenues	15,453	158,852	138,113	(35,490)	276,928
Cost of sales	14,979	119,964	67,626	(35,882)	166,687
Gross profit	474	38,888	70,487	392	110,241
Operating expenses:					
Research and development	181	2,278	20,806		23,265
Sales and marketing	1,483	18,924	22,429		42,836
General and administrative	7,851	11,453	19,206		38,510
Total operating expenses	9,515	32,655	62,441		104,611
Operating (loss) income	(9,041)	6,233	8,046	392	5,630
Equity in earnings of subsidiaries, net of tax	4,983			(4,983)	
Interest expense, including amortization of discounts and write off of deferred financing costs	(11,255)	(5,015)	(3,604)	2,717	(17,157)
Other income, net	2,880	612	880	(2,717)	1,655
(Loss) income before income taxes	(12,433)	1,830	5,322	(4,591)	(9,872)
Income tax provision	563	1,462	1,099		3,124
Net (loss) income	$ (12,996)	$ 368	$ 4,223	$ (4,591)	$ (12,996)

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING BALANCE SHEET

September 30, 2005

(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
ASSETS					
Current Assets:					
Cash and cash equivalents	$ 822	$ 8,511	$ 20,640	$	$ 29,973
Accounts receivable, net of allowances	2,832	31,868	38,185		72,885
Inventories	6,537	46,164	25,682	(5,416)	72,967
Deferred tax assets		142	2,819		2,961
Prepaid expenses and other current assets	1,527	2,932	9,295		13,754
Intercompany receivables	33,926	26,778	15,593	(76,297)	
Total current assets	45,644	116,395	112,214	(81,713)	192,540
Property, plant and equipment, net	2,738	32,729	36,255		71,722
Goodwill	78,223	109,116	130,783		318,122
Other intangible assets with indefinite lives	10,000	12,420	50,168		72,588
Core technology and patents, net	30,336	5,912	30,639		66,887
Other intangible assets, net	9,823	18,800	24,935		53,558
Deferred financing costs, net, and other non-current assets	5,841	2,489	4,493		12,823
Deferred tax assets	13,760		574	46	14,380
Investment in subsidiaries	300,032	(1,148)		(298,884)	
Intercompany notes receivable	134,620	43,066		(177,686)	
Total assets	$ 631,017	$ 339,779	$ 390,061	$ (558,237)	$ 802,620
LIABILITIES AND STOCKHOLDERS EQUITY					
Current liabilities:					
Current portion of long-term debt	$	$	$ 2,391	$	$ 2,391
Current portion of capital lease obligations		507	36		543
Accounts payable	2,194	23,555	14,148		39,897
Accrued expenses and other current liabilities	10,816	26,458	40,315		77,589
Intercompany payables	27,974	23,311	25,012	(76,297)	
Total current liabilities	40,984	73,831	81,902	(76,297)	120,420
Long-term liabilities:					
Long-term debt, net of current portion	169,406	49,070	25,065		243,541
Capital lease obligations, net of current portion		1,050	72		1,122
Deferred tax liabilities	15,448	5,453	6,915		27,816
Other long-term liabilities		281	4,261		4,542
Intercompany notes payable		52,331	125,355	(177,686)	

Total long-term liabilities	184,854	108,185	161,668	(177,686)	277,021
Stockholders equity	405,179	157,763	146,491	(304,254)	405,179
Total liabilities and stockholders equity	$ 631,017	$ 339,779	$ 390,061	$ (558,237)	$ 802,620

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING BALANCE SHEET

December 31, 2004

(in thousands)

(unaudited)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
ASSETS					
Current Assets:					
Cash and cash equivalents.	$ 12	$ 3,551	$ 13,193	$	$ 16,756
Accounts receivable, net of allowances	2,660	36,273	22,414	-	61,347
Inventories	6,340	41,152	19,815	(6,073)	61,234
Deferred tax assets	-		2,819		2,819
Prepaid expenses and other current assets	1,278	2,034	6,289		9,601
Intercompany receivables	54,358	10,015	14,145	(78,518)	
Total current assets	64,648	93,025	78,675	(84,591)	151,757
Property, plant and equipment, net	2,808	27,591	36,381		66,780
Goodwill	17,672	108,842	94,641		221,155
Other intangible assets with indefinite lives		12,420	38,122		50,542
Core technology and patents, net	2,533	6,009	31,785		40,327
Other intangible assets, net		20,522	7,158		27,680
Deferred financing costs, net, and other non-current assets	6,452	1,710	994		9,156
Deferred tax assets			826	46	872
Investment in subsidiaries	261,274	(966)		(260,308)	
Intercompany notes receivable	114,439	15,089		(129,528)	
Total assets	$ 469,826	$ 284,242	$ 288,582	$ (474,381)	$ 568,269
LIABILITIES AND STOCKHOLDERS EQUITY					
Current liabilities:					
Current portion of long-term debt	$	$	$ 88	$	$ 88
Current portion of capital lease obligations		461	6		467
Accounts payable	1,754	19,497	11,094		32,345
Accrued expenses and other current liabilities	12,408	21,654	22,180		56,242
Intercompany payables	13,640	15,964	48,914	(78,518)	
Total current liabilities	27,802	57,576	82,282	(78,518)	89,142
Long-term liabilities:					
Long-term debt, net of current portion	169,256	20,000	12		189,268
Capital lease obligations, net of current portion		1,397	4		1,401

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

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF CASH FLOWS

For the Nine Months Ended September 30, 2005

(unaudited)

(in thousands)

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

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

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF CASH FLOWS

For the Nine Months Ended September 30, 2004

(unaudited)

(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Operating Activities:					
Net (loss) income	$ (12,996)	$ 368	$ 4,223	$ (4,591)	$ (12,996)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:					
Equity in earnings of subsidiaries, net of tax	(4,983)			4,983	
Interest expense related to amortization and/or write-off of non-cash original issue discount, and deferred financing costs	843	3,151	386		4,380
Noncash (gains) losses related to interest rate swap and currency hedge agreements	(432)		106		(326)
Depreciation and amortization	1,135	6,201	10,305		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	(1,284)	(2,238)		(1,717)
Inventories	(1,399)	(4,111)	(3,332)	(431)	(9,273)
Prepaid expenses and other current assets	(1,008)	22	797		(189)
Intercompany payables or receivables	10,443	(9,703)	(858)	118	
Accounts payable	(3,290)	1,350	(1,446)		(3,386)
Accrued expenses and other current liabilities	2,301	(1,490)	6,157		6,968
Increase in other long-term liabilities		29	460		489
Net cash (used in) provided by operating activities	(7,245)	(3,879)	14,488	79	3,443

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Investing Activities:					
Purchases of property, plant and equipment	(1,531)	(6,004)	(7,868)		(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)	183	(564)		(1,129)
Net cash used in investing activities	(6,992)	(7,268)	(14,363)		(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		(7,821)	(23,278)		(31,099)
Repayments of notes payable	(9,000)	(75,762)	(10,002)		(94,764)
Principal payments of capital lease obligations		(358)	(4)		(362)
Intercompany notes payable or receivable	(124,809)	91,949	32,860		
Net cash provided by (used in) financing activities	12,761	7,617	(520)		19,858
Foreign exchange effect on cash and cash equivalents		(17)	(260)	(79)	(356)
Net decrease in cash and cash equivalents	(1,476)	(3,547)	(655)		(5,678)
Cash and cash equivalents, beginning of period	1,708	11,315	11,599		24,622
Cash and cash equivalents, end of period	$ 232	$ 7,768	$ 10,944	$	$ 18,944

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 research and development expenditures, anticipated growth, benefits to be realized as a result of synergies relating to our acquisitions, benefits to be realized from our joint venture agreement with PBM related to drugs of abuse diagnostic products, 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.

Financial Overview

For the three and nine months ended September 30, 2005, we recorded net revenue of $106.3 million and $300.5 million, respectively, compared to net revenue of $96.7 million and $276.9 million for the three and nine months ended September 30, 2004, respectively. Overall revenue growth, adjusted for the impact of currency translation, resulted principally from acquisitions, which occurred primarily in our professional diagnostics business.

Despite the growth in our revenue, for the three and nine months ended September 30, 2005, we recorded a net loss of $6.6 million and $11.9 million, respectively, compared to net loss of $2.9 million and $13.0 million for the three and nine months ended September 30, 2004, respectively. Factors that contributed to the lower loss in 2005 through September, as compared to the loss in the comparable period of 2004, include net settlement and litigation gains totaling $19.1 million offset by (i) a $4.1 million charge associated with our previously announced decision to close one of our manufacturing facilities, (ii) a $1.6 million non-recurring charge for a product recall, and (iii) a $2.4 million charge associated with a reserve established during the second quarter of 2005 at our Wampole subsidiary for excess quantities of certain raw materials and finished goods, including certain finished goods held at distributors but subject to rights of return.

As a leading global developer of advanced diagnostic devices, we are continually exploring opportunities in a variety of professional diagnostic and consumer-oriented applications, including immuno-diagnostics with a focus on women s health, cardiology and infectious disease. Our emphasis on new product development requires substantial investment and involves significant inherent risk. We intend to continue to devote substantial resources to research and development activities. Our co-development agreement with ITI Scotland Ltd., or ITI Scotland, who will provide us with £30 million over three years to fund certain new and existing cardiovascular-related research and development initiatives, as well as development of our new cardiac center in Stirling, Scotland, is evidence of this commitment. In addition, we will continue to aggressively defend our substantial intellectual property portfolio, which underlies our emphasis on new product development, against potential infringers.

Our Acquisition of the Rapid Diagnostics Business from Abbott Laboratories

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

In ultimately agreeing to pay the purchase price, our investment rationale focused specifically on (i) significant operating and marketing synergies that we believed would result in cost savings and therefore increased profits on a combined basis and (ii) strategic revenue and market growth objectives. We expected that the operating synergies would be achieved by adding the Fact plus volumes not currently manufactured by us and by taking over from other third party manufacturers and Abbott the manufacturing of the Signify

and TestPack products. We believed that these benefits would arise both from efficiencies related to increased volume but also in part from the redesign of the products. We expected that the marketing synergies would arise as we leveraged our existing sales staff by adding Fact plus to our existing consumer diagnostics distribution capability.

With respect to marketing synergies, we have enjoyed the savings that we anticipated at the time of the acquisition with respect to the addition of the Fact plus product line to our existing consumer diagnostics business, which has sold and distributed Fact plus with nominal increases in consumer sales and marketing infrastructure.

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

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 manufacturing transition was completed in the third quarter of 2005. We currently anticipate achieving synergies in line with our expectations as of the date of acquisition. Additional manufacturing synergies were anticipated as we transition production of home pregnancy tests for the international market to our own manufacturing operations. We began this transition by taking over production of Fact plus made for sale to one very small target market in the second quarter of 2004 and we transitioned the vast majority of production of the pregnancy tests acquired from Abbott for the international markets in the fourth quarter of 2004 which, along with improved pricing due to distribution changes, resulted in increased gross margins on the acquired home pregnancy tests since 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 entitled Certain Factors Affecting Future Results and Special Statement Regarding Forward-Looking Statements.

Results of Operations

Net Revenue. Net revenue increased by $9.6 million, or 10%, to $106.3 million for the three months ended September 30, 2005 from $96.7 million for the three months ended September 30, 2004. Net revenue increased by $23.6 million, or 9%, to $300.5 million for the nine months ended September 30, 2005 from $276.9 million for the nine months ended September 30, 2004. The factors resulting in the changes in net revenue for each comparative period are discussed in the Net Product Sales, Total and by Business Segment and License Revenue discussions which follow.

Net Product Sales, Total and by Business Segment. Net product sales increased by $7.9 million, or 9%, to $101.8 million for the three months ended September 30, 2005 from $93.9 million for the three months ended September 30, 2004. Net product sales increased by $19.7 million, or 7%, to $289.3 million for the nine months ended September 30, 2005 from $269.6 million for the nine months ended September 30, 2004. Adjusted for the impact of currency translation on our foreign operations, total net product sales in the three and nine months ended September 30, 2005 grew by approximately $8.2 million, or 9%, and $18.2 million, or 7%, respectively, compared to the same periods in 2004.

Net product sales by business segment for the three and nine months ended September 30, 2005 and 2004, respectively, are as follows:

(in thousands)	Three Months ended September 30, 2005	2004	% Increase (Decrease)	Nine Months ended September 30, 2005	2004	% Increase (Decrease)
Consumer diagnostic products	$ 38,939	$ 45,187	(14)%	$ 122,866	$ 120,411	2%
Vitamins and nutritional supplements	19,395	17,409	11%	55,234	56,234	(2)%
Professional diagnostic products	43,474	31,274	39%	111,180	92,979	20%
Total net product sales	$ 101,808	$ 93,870	9%	$ 289,280	$ 269,624	7%

Adjusted for currency translation impact, net product sales of our consumer diagnostic products decreased by $6.1 million, or 13%, comparing the three months ended September 30, 2005 to the three months ended September 30, 2004 and increased $1.5 million, or 1%, comparing the nine months ended September 30, 2005 to the nine months ended September 30, 2004. The decrease in revenues for the three month period ended September 30, 2005 compared to 2004 relates primarily to lower sales of e.p.t. pregnancy

tests under our supply arrangement with Pfizer. The increase in the nine month period represents $1.3 million of sales contributed from our acquisition of ACS in January 2005 and organic growth in our premium pregnancy test products.

Our vitamins and nutritional supplements business grew by $2.0 million, or 11%, comparing the three months ended September 30, 2005 to the three months ended September 30, 2004 and declined by $1.0 million, or 2%, comparing the nine months ended September 30, 2005 to the nine months ended September 30, 2004. Sales decreased by $3.1 million comparing the nine months ended September 30, 2005 to the nine months ended September 30, 2004, due to a decline in sales of vitamin E as a result of recent negative industry-wide publicity concerning the efficacy of vitamin E. The decrease in vitamin E sales during the nine months ended September 30, 2005 was partially offset by an increase in contract manufacturing sales to third party nutritional suppliers. Our vitamins and nutritional supplements business continues to face significant competition due to continued excess capacity in the industry.

Adjusted for currency translation impact, net product sales of our professional diagnostic products increased by $12.3 million, or 39%, comparing the three months ended September 30, 2005 to the three months ended September 30, 2004 and increased by $17.8 million, or 19%, comparing the nine months ended September 30, 2005 to the nine months ended September 30, 2004. Our acquisition of the Determine/Dana Screen Rapid Diagnostics business in June 2005, Binax in March 2005 and Viva Diagnostika in June 2004, contributed $16.7 million and $25.5 million of net product sales for the three and nine month periods ended September 30, 2005 compared to $1.5 million and $1.9 million for the three and nine month periods ended September 30, 2004, which represents only sales related to Viva Diagnostika. Excluding the impact from currency translation and acquisitions, net product sales of our professional diagnostic products decreased by $2.9 million and $5.8 million, respectively, comparing the three and nine month periods ended September 30, 2005 to the three month and nine month periods ended September 30, 2004. The decline in sales of our professional diagnostic products primarily resulted from decreased sales of rapid diagnostic tests during the three months ended September 30, 2005 at our Wampole subsidiary and, as it relates to both the three and nine month periods, from decreased sales of certain of our drugs of abuse diagnostic products due to an FDA issue at our subsidiary Applied Biotech, Inc., or ABI. See detailed discussion of the FDA issue at ABI in the risk factor entitled Our failure to meet strict regulatory requirements could require us to pay fines, incur other costs or even close our facilities in the section entitled Certain Factors Affecting Future Results included herein. In addition, during the first quarter of 2005, we recorded a $0.3 million specific returns reserve, which reduced our net product sales, due to a recall of two of our drugs of abuse diagnostic products following our decision to withdraw the products 510(k)s. The products impacted by the recall contributed approximately 1% of our consolidated net revenues in 2004. We believe that a joint venture related to drugs of abuse products that we have agreed to establish with PBM pursuant to our settlement with them should to a great extent replace these recalled products.

License Revenue. License revenue represents license and royalty fees from intellectual property license agreements with third-parties. License revenue increased by $1.7 million, or 61%, to $4.5 million for the three months ended September 30, 2005 from $2.8 million for the three months ended September 30, 2004 and by $3.9 million, or 53%, to $11.2 million for the nine months ended September 30, 2005 from $7.3 million for the nine months ended September 30, 2004. The increases for both the three and nine month periods primarily relate to royalty revenues received as a result of the settlement and licensing arrangement that we entered into with Quidel in April 2005.

Gross Profit and Margin. Gross profit increased by $1.9 million, or 5%, to $39.6 million for the three months ended September 30, 2005 from $37.7 million for the three months ended September 30, 2004. Gross profit decreased by $3.7 million, or 3%, to $106.5 million for the nine months ended September 30, 2005 from $110.2 million for the nine months ended September 30, 2004. The gross profit increase for the three months ended September 30, 2005 resulted principally from the gross profit earned on increased professional diagnostics products and license revenue, as discussed above. The gross profit decrease, comparing the nine months ended September 30, 2005 to the nine months ended September 30, 2004, resulted from: (i) the inclusion in cost of sales in the nine month period ended September 30, 2005 of a $3.5 million charge associated with our decision to close our CDIL manufacturing facility, (ii) a charge of $2.4 million associated with a reserve established during the second quarter of 2005 at our Wampole subsidiary for excess quantities of certain raw materials and finished goods, including certain finished goods held at distributors but subject to rights of return, and (iii) a $1.6 million provision for returns and inventory reserve which was established as a result of our recall of the drugs of abuse diagnostic products during the first quarter of 2005, offset in part by the gross profit earned on increased professional diagnostics products and license revenue, as discussed above. Gross profit from our nutritional supplements business increased by $0.3 million comparing the three months ended September 30, 2005 to the three months ended September 30, 2004 but

decreased $2.5 million comparing the nine months ended September 30, 2005 to the nine months ended September 30, 2004. Our private label nutritional supplements business has suffered from excess capacity in the industry which led to increasing price competition.

Overall gross margin was 37% and 35% for the three and nine months ended September 30, 2005 compared to 39% and 40% for the three and nine months ended September 30, 2004, respectively. Overall gross margin in 2005 was adversely affected by the $3.5 million CDIL closure costs, the $2.4 million Wampole inventory reserve, and the $1.6 million returns and inventory reserve associated with the drugs of abuse product recalls discussed above. Excluding these charges, gross margin was 38% for both the three and nine month periods ended September 30, 2005.

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 $0.7 million, or 2%, to $36.4 million for the three months ended September 30, 2005 from $35.7 million for the three months ended September 30, 2004. Gross profit from total net product sales decreased by $6.8 million, or 6%, to $98.6 million for the nine months ended September 30, 2005 from $105.4 million for the nine months ended September 30, 2004.

Gross profit from net product sales by business segment for the three and nine months ended September 30, 2005 and 2004, respectively, are as follows:

(in thousands)	Three Months ended September 30, 2005	2004	% Increase (Decrease)	Nine Months ended September 30, 2005	2004	% Increase (Decrease)
Consumer diagnostic products	$ 18,819	$ 22,825	(18)%	$ 58,291	$ 63,455	(8)%
Vitamins and nutritional supplements	1,479	1,205	23%	3,406	5,934	(43)%
Professional diagnostic products	16,087	11,694	38%	36,931	36,022	3%
Total gross profit from net product sales	$ 36,385	$ 35,724	2%	$ 98,628	$ 105,411	(6)%

Gross profit in our consumer products segment decreased by $4.0 million and $5.2 million comparing the three and nine months ended September 30, 2005 to the three and nine months ended September 30, 2004, respectively. Included in cost of sales for the three and nine months ended September 30, 2005 was a $0.6 million and $3.5 million, respectively, charge associated with our decision to close our CDIL manufacturing facility. Excluding this charge, gross profit from our consumer products segment decreased by $3.4 million and $1.7 million comparing the three and nine months ended September 30, 2005 to the three and nine months ended September 30, 2004, respectively. Including the charge recorded in the second quarter, we expect the total restructuring charge related to the closure of CDIL to be approximately $6.3 million, with additional charges relating principally to severance and facility closing costs of $1.9 million expected to be recorded in the fourth quarter of 2005 and $0.3 million expected to be recorded in the first quarter of 2006.

Gross margin from our consumer product sales was 48% and 47% for the three and nine months ended September 30, 2005, respectively, compared to 51% and 53% for the three and nine months ended September 30, 2004, respectively. Excluding the CDIL closure charge discussed above, gross margin from our consumer products segment was 50% for both the three and nine months ended September 30, 2005. The remaining decrease in gross margin from our consumer diagnostic product sales resulted from change in product mix.

Gross profit in our vitamins and nutritional supplement business increased by $0.3 million comparing the three month period ended September 30, 2005 to the three month period ended September 30, 2004 and decreased $2.5 million comparing the nine months ended September 30, 2005 to the nine months ended September 30, 2004. Our private label nutritional supplements business has suffered from excess capacity in the industry which led to increasing price competition and generally decreasing margins.

Gross profit in our professional diagnostic products segment increased by $4.4 million and $0.9 million comparing the three and nine months ended September 30, 2005 to the three and nine months ended September 30, 2004, respectively. Gross profit increased during the three months ended September 30, 2005 principally as a result of gross profit earned on revenues from acquired business, as discussed above. Reducing gross margin for the nine months ended September 30, 2005 were a charge of $2.4 million associated with a reserve established during the second quarter of 2005 at our Wampole subsidiary for excess quantities of certain raw materials and finished goods, including certain finished goods

held at distributors but subject to rights of return and a $1.6 million provision for returns and inventory reserve which were established as a result of our recall of the drugs of abuse diagnostic products during the first quarter of 2005. Excluding these charges, gross profit from our professional diagnostic products segment increased by $4.9 million comparing the nine months ended September 30, 2005 to the nine months ended September 30, 2004, respectively.

Gross margin from our professional diagnostic product sales was 37% and 33% for the three and nine months ended September 30, 2005, respectively, compared to 37% and 39% for the three and nine months ended September 30, 2004, respectively. Excluding the $2.4 million Wampole inventory reserve and the $1.6 million drugs of abuse charge discussed above, gross margin from our professional diagnostic product sales was 37% for the nine months ended September 30, 2005.

Research and Development Expense. Research and development expense increased by $0.1 million, or 2%, to $8.0 million for the three months ended September 30, 2005 from $7.9 million for the three months ended September 30, 2004. Research and development expense decreased by $2.7 million, or 12%, to $20.6 million for the nine months ended September 30, 2005 from $23.3 million for the nine months ended September 30, 2004. Research and development expense is reported net of co-development funding of $3.8 million and $12.6 million recognized during the three and nine months ended September 30, 2005, respectively, arising from the co-development funding arrangement that we entered into with ITI Scotland in February 2005. Research and development expense before considering the co-development funding was $11.8 million and $33.2 million for the three and nine months ended September 30, 2005, respectively, an increase of $4.0 million and $9.9 million, respectively, from the corresponding prior year periods.

The increase in spending resulted in part from increased spending of $1.1 million and $2.4 million, comparing the three and nine months ended September 30, 2005 to the same periods in 2004, respectively, primarily in our professional diagnostics business associated with our acquisitions of Binax and Ischemia. The remaining research and development spending of $2.9 million and $7.5 million, comparing the three and nine months ended September 30, 2005 to the same periods in 2004, respectively, primarily related to our continued significant investment in the development of products in the field of cardiology.

Sales and Marketing Expense. Sales and marketing expense increased by $2.9 million, or 19%, to $17.7 million for the three months ended September 30, 2005 from $14.8 million for the three months ended September 30, 2004. Sales and marketing expense increased by $9.6 million, or 22%, to $52.4 million for the nine months ended September 30, 2005 from $42.8 million for the nine months ended September 30, 2004. Approximately $0.6 million and $3.7 million of the increase in sales and marketing expenses, comparing the three and nine months ended September 30, 2005 to the same periods in 2004, respectively, resulted from our advertising efforts to promote our premium consumer diagnostic products in 2005. Approximately $1.5 million and $3.6 million, comparing the three and nine months ended September 30, 2005 to the same periods in 2004, respectively, of the increase in sales and marketing expenses resulted from acquisitions. The remaining increase in sales and marketing expenses of $0.8 million and $2.3 million comparing the three and nine months ended September 30, 2005 to the same periods in 2004, respectively, primarily resulted from our expanded sales and marketing infrastructure to support the anticipated growth in our professional diagnostics business.

Sales and marketing expense as a percentage of net product sales increased to 17% and 18% for the three and nine months ended September 30, 2005, respectively, from 16% for the three and nine months ended September 30, 2004. The increase in sales and marketing expense as a percentage of net product sales primarily resulted from our investment in advertising efforts of our premium consumer diagnostic products and sales and marketing infrastructure to support our anticipated growth in the professional diagnostics business.

General and Administrative Expense. General and administrative expense increased by $1.3 million, or 10%, to $14.4 million for the three months ended September 30, 2005 from $13.1 million for the three months ended September 30, 2004. General and administrative expense increased by $6.3 million, or 16%, to $44.8 million for the nine months ended September 30, 2005 from $38.5 million for the nine months ended September 30, 2004. Approximately $0.9 million and $3.6 million, respectively, for the three and nine months ended September 30, 2005, of the increase in general and administrative expense resulted from acquisitions. The remaining increase in general and administrative expense, comparing the three and nine months ended September 30, 2005 to the same periods in 2004, $0.4 million and $2.6 million, respectively, resulted from an increase in consulting and legal spending, due to the investigations at Wampole and our active pursuits and defenses in litigations, including our lawsuits and settlements with Quidel and PBM.

General and administrative expense as a percentage of net product sales was 14% and 15% for the three and nine months ended September 30, 2005, respectively, compared to 14% for both the three and nine months ended September 30, 2004.

Interest Expense. Interest expense includes interest charges, the write-off and amortization of deferred financing costs and the amortization of non-cash discounts associated with our debt issuances 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 $0.7 million, or 15%, to $5.5 million for the three months ended September 30, 2005 from $4.8 million for the three months ended September 30, 2004. Interest expense decreased by $1.8 million, or 10%, to $15.4 million for the nine months ended September 30, 2005 from $17.2 million for the nine months ended September 30, 2004. 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 $0.6 million and $2.0 million, comparing the three and nine months ended September 30, 2005 to the same periods in 2004, respectively. Such increase was primarily due to a higher average outstanding debt balance which was $219.4 million during the nine months ended September 30, 2005, compared to $188.1 million during the nine months ended September 30, 2004, primarily as a result of the borrowings to finance various acquisitions and operations. Additionally, the 8.75% interest rate on the $150.0 million bonds, together with its 50 basis points interest penalty during a portion of

the first quarter of 2005 due to the late registration of the related exchange offer, increased our average cash interest rate to 9.25% for the nine months ended September 30, 2005 from 8.5% for the nine months ended September 30, 2004. The bonds, which are due in 2012, provide us with a long-term fixed rate on a significant portion of our indebtedness, as compared to the variable rates under our senior credit facility.

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

(in thousands)	Three Months ended September 30, 2005	2004	Nine Months ended September 30, 2005	2004
Interest income	$ 259	$ 234	$ 764	$ 806
Foreign exchange (losses) gains, net	(233)	166	(350)	15
Other	269	779	19,665	834
Total other income, net	$ 295	$ 1,179	$ 20,079	$ 1,655

Included in other income, net, for the nine months ended September 30, 2005 was $15.0 million in income, being the portion of our settlement with Quidel relating to periods prior to 2005, an $8.4 million gain from a legal settlement of class action suit against several raw material suppliers in our vitamins and nutritional supplements business and $2.6 million related to the value of an option received under a licensing arrangement entered into during the quarter, offset by a $2.7 million charge related to a legal settlement of a nutritional segment commercial dispute arising from a distribution arrangement entered into in September 1996 and a $4.3 million charge related to a legal settlement with PBM.

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.

Income Tax Provision. During the three and nine months ended September 30, 2005, we recorded an income tax provision of $1.0 million and $5.4 million, respectively, compared to $1.2 million and $3.1 million for the three and nine months ended September 30, 2004, respectively. The significant increase in the income tax provision for the nine months ended September 30, 2005 related to the foreign and state income tax provisions as a result of legal settlements, as discussed above, and to foreign income tax provisions for profits arising from the business operations of certain of our foreign subsidiaries.

Net (Loss) Income. We incurred a net loss for the three and nine months ended September 30, 2005 of $6.6 million and $11.9 million, respectively, while for the three and nine months ended September 30, 2004, we incurred a net loss of $2.9 million and $13.0 million, respectively. After taking into account charges for redemption premium an