

INVERNESS MEDICAL INNOVATIONS INC
Form 10-Q
August 15, 2005

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
for the quarterly period ended **June 30, 2005**

OR

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

COMMISSION FILE NUMBER 001-16789

INVERNESS MEDICAL INNOVATIONS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

DELAWARE
(State or other jurisdiction of
incorporation or organization)

04-3565120
(I.R.S. Employer
Identification No.)

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51 SAWYER ROAD, SUITE 200

WALTHAM, MASSACHUSETTS 02453

(Address of principal executive offices)

(781) 647-3900

(Registrant's Telephone Number, Including Area Code)

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

Yes No

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

Yes No

The number of shares outstanding of the registrant's common stock as of August 6, 2005 was 27,341,546.

INVERNESS MEDICAL INNOVATIONS, INC.

FORM 10-Q

For the Quarterly Period Ended June 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 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 41 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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EXPLANATORY NOTE

On June 28, 2005, we announced that certain of our previously issued financial statements must be restated because they contain errors under accounting principles generally accepted in the United States (GAAP) relating to the recognition of revenue at one of our diagnostic divisions. We had determined that certain customers of this division were provided return or exchange rights in connection with the sale of products, as a result of which the revenues associated with these sales should not have been recognized upon shipment to the customers under GAAP. Since that time the Audit Committee of our Board of Directors conducted an investigation into these matters using independent special counsel. The results of this investigation contributed to our determination that the necessary restatement required \$4.2 million in net revenue reversal with a \$3.1 million gross margin and corresponding net loss impact spread over the quarters of 2003 and 2004 and the first quarter of 2005. In addition, we have taken an inventory write off of \$2.4 million related to excess quantities of raw material and finished goods for product at the diagnostic division, which is recorded as a cost of sales in the second quarter of 2005.

Our financial statements included in this quarterly report on Form 10-Q reflect the results of the matters discussed above. In addition, we intend to restate our audited financial statements for the fiscal years ended December 31, 2004 and December 31, 2003 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2004, as well as our unaudited financial statements for the periods ended September 30, 2004 and September 30, 2003 included in Amendment No. 1 to our Quarterly Report on Form 10-Q/A for the period ended September 30, 2004, and our unaudited financial statements for the periods ended March 31, 2005 and March 31, 2004 included in our Quarterly Report on Form 10-Q for the period ended March 31, 2005.

Included in net income (loss) for the three and six month periods ended June 30, 2005 is an after tax charge of \$0.5 million relating to a change in the fair value of certain forward foreign exchange contracts not deemed to be hedges for accounting purposes, which was not included in our preliminary net income (loss) under GAAP reported in our earnings release dated August 3, 2005.

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 June 30,		Six Months Ended June 30,	
	2005	2004 (restated)	2005	2004 (restated)
Net product sales	\$ 97,773	\$ 87,146	\$ 187,472	\$ 175,754
License revenue	4,498	1,997	6,719	4,497
Net revenue	102,271	89,143	194,191	180,251
Cost of sales	67,558	53,815	127,289	107,726
Gross profit	34,713	35,328	66,902	72,525
Operating expenses:				
Research and development (Note 10)	5,360	7,992	12,592	15,415
Sales and marketing	17,666	13,661	34,696	28,012
General and administrative	16,242	14,137	30,357	25,457
Total operating expenses	39,268	35,790	77,645	68,884
Operating (loss) income	(4,555)	(462)	(10,743)	3,641
Interest expense, including amortization of discounts and write-off of deferred financing costs	(4,960)	(4,541)	(9,972)	(12,311)
Other income, net (Note 14)	14,872	29	19,783	476
Income (loss) before income taxes	5,357	(4,974)	(932)	(8,194)
Income tax provision	2,854	1,759	4,367	1,922
Net income (loss)	\$ 2,503	\$ (6,733)	\$ (5,299)	\$ (10,116)
Net income (loss) available to common stockholders basic and diluted (Note 6)	\$ 2,503	\$ (6,733)	\$ (5,299)	\$ (10,865)
Net income (loss) per common share basic (Note 6)	\$ 0.11	\$ (0.34)	\$ (0.24)	\$ (0.56)
Net income (loss) per common share diluted (Note 6)	\$ 0.10	\$ (0.34)	\$ (0.24)	\$ (0.56)
Weighted average shares basic (Note 6)	23,127	19,701	22,040	19,568
Weighted average shares diluted (Note 6)	24,627	19,701	22,040	19,568

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)

	June 30, 2005	December 31, 2004 (restated)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 28,886	\$ 16,756
Accounts receivable, net of allowances of \$9,294 at June 30, 2005 and \$9,359 at December 31, 2004	51,128	61,347
Inventories, net	66,029	61,234
Deferred tax assets	2,961	2,819
Prepaid expenses and other current assets	14,263	9,601
Total current assets	163,267	151,757
Property, plant and equipment, net	68,034	66,780
Goodwill	278,197	221,155
Other intangible assets with indefinite lives	65,105	50,542
Core technology and patents, net	67,672	40,327
Other intangible assets, net	45,078	27,680
Deferred financing costs, net, and other non-current assets	12,773	9,156
Deferred tax assets	16,262	872
Total assets	\$ 716,388	\$ 568,269
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Current portion of long-term debt	\$ 359	\$ 88
Current portion of capital lease obligations	502	467
Accounts payable	34,869	32,345
Accrued expenses and other current liabilities	66,741	56,242
Total current liabilities	102,471	89,142
Long-term liabilities:		
Long-term debt, net of current portion	258,432	189,268
Capital lease obligations, net of current portion	1,180	1,401
Deferred tax liabilities	29,092	12,596
Other long-term liabilities	4,855	4,446
Total long-term liabilities	293,559	207,711
Commitments and contingencies (Note 14)		
Series A redeemable convertible preferred stock, \$0.001 par value:		
Authorized 2,667 shares		
Issued 2,527 shares		
Outstanding none		
Stockholders equity:		
Preferred stock, \$0.001 par value:		
Authorized 2,333 shares, none issued		
Common stock, \$0.001 par value:		
Authorized 50,000 shares		
Issued and outstanding 23,290 shares at June 30, 2005 and 20,711 shares at December 31, 2004	23	21
Additional paid-in capital	419,901	359,582
Notes receivable from stockholders	(14,691)	(14,691)
Accumulated deficit	(96,316)	(91,017)

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Accumulated other comprehensive income	11,441	17,521
Total stockholders equity	320,358	271,416
Total liabilities and stockholders equity	\$ 716,388	\$ 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)

	Six Months Ended June 30,	
	2005	2004 (restated)
Cash Flows from Operating Activities:		
Net loss	\$ (5,299)	\$ (10,116)
Adjustments to reconcile 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	899	3,960
Noncash gain related to interest rate swap agreement		(434)
Noncash stock-based compensation expense	140	
Depreciation and amortization	12,685	11,379
Deferred income taxes	1,276	1,282
Other noncash items	594	(79)
Changes in assets and liabilities, net of acquisitions:		
Accounts receivable, net	14,407	2,569
Inventories	(2,308)	(6,448)
Prepaid expenses and other current assets	(5,629)	1,430
Accounts payable	364	(6,508)
Accrued expenses and other current liabilities	11,646	8,711
Other long-term liabilities	433	302
Net cash provided by operating activities	29,208	6,048
Cash Flows from Investing Activities:		
Purchases of property, plant and equipment	(9,135)	(9,925)
Proceeds from sale of property, plant and equipment	151	182
Payments for acquisitions and intellectual property	(74,696)	(8,486)
Increase in other assets	(788)	(794)
Net cash used in investing activities	(84,468)	(19,023)
Cash Flows from Financing Activities:		
Cash paid for financing costs	(2,058)	(5,117)
Proceeds from issuance of common stock, net of issuance costs	2,222	546
Proceeds from issuance of senior subordinated notes		150,000
Net proceeds (repayment) from revolving lines of credit	49,172	(39,958)
Net borrowing (repayments) of notes payable	20,086	(94,505)
Principal payments of capital lease obligations	(237)	(242)
Net cash provided by financing activities	69,185	10,724
Foreign exchange effect on cash and cash equivalents	(1,795)	(376)
Net increase (decrease) in cash and cash equivalents	12,130	(2,627)
Cash and cash equivalents, beginning of period	16,756	24,622
Cash and cash equivalents, end of period	\$ 28,886	\$ 21,995
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 for the year ended December 31, 2004. 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 which, as noted below, are going to be restated and included in an amendment to our annual report on Form 10-K for the year ended December 31, 2004.

We are restating the financial results of our previously issued consolidated financial statements as of June 30, 2004 and for the three and six months ended June 30, 2004, and the three months ended March 31, 2004, to correct errors under GAAP relating to the recognition of revenue. Such adjustments are reflected in the accompanying consolidated interim financial information for the three and six months ended June 30, 2004 and for the year the year ended December 31, 2004, as discussed in Note 2 below.

(2) Restatement

We are restating the financial results of our previously issued consolidated financial statements as of June 30, 2004 and for the three and six month periods ended June 30, 2004, respectively, to correct errors under GAAP relating to the recognition of revenue. We determined that certain customers of one of our diagnostics divisions were provided return or exchange rights in connection with the sale of products, as a result of which the revenue associated with those sales should not have been recognized upon shipment to the customers under GAAP. As a result, we recorded \$4.2 million in net revenue reversal with a \$3.1 million gross margin and corresponding net loss impact spread over the quarters of 2003 and 2004 and the first quarter of 2005. In addition, we have recorded an inventory write off of \$2.4 million related to excess quantities of raw materials and finished goods for product at our Wampole division which is recorded as a cost of sales in the second quarter of 2005.

Our financial statements included in this quarterly report on Form 10-Q reflect the results of the matters discussed above. In addition, we intend to restate our audited financial statements for the fiscal years ended December 31, 2004 and December 31, 2003 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2004, as well as our unaudited financial statements for the periods ended September 30, 2004 and September 30, 2003 included in Amendment No. 1 to our Quarterly Report on Form 10-Q/A for the period ended September 30, 2004, and our unaudited financial statements for the periods ended March 31, 2005 and March 31, 2004 included in our Quarterly Report on Form 10-Q for the period ended March 31, 2005.

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

(in thousands, except per share amounts)	Three Months Ended June 30, 2004		Six Months Ended June 30, 2004	
	As restated	As reported	As restated	As reported
Net revenues	\$ 89,143	\$ 88,727	\$ 180,251	\$ 179,428
Cost of sales	53,815	53,723	107,726	107,515
Net loss	(6,733)	(7,057)	(10,116)	(10,728)
Net loss available to common stockholders basic and diluted	(6,733)	(7,057)	\$ (10,865)	\$ (11,477)
Pro forma net loss per common share and diluted	\$ (0.34)	\$ (0.36)	\$ (0.56)	\$ (0.59)

(in thousands, except per share amounts)	December 31, 2004	
	As restated	As reported
Inventories	\$ 61,234	\$ 60,143
Accrued expenses and other current liabilities	56,242	51,886
Accumulated Deficit	91,017	87,752

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

(3) Cash and Cash Equivalents

We consider all highly liquid cash investments with original maturities of three months or less at the date of acquisition to be cash equivalents. At June 30, 2005, our cash equivalents consisted of money market funds.

(4) Inventories

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

(in thousands)	June 30, 2005	December 31, 2004
Raw materials	\$ 27,552	\$ 23,434
Work-in-process	16,133	14,956
Finished goods	22,344	22,844
	\$ 66,029	\$ 61,234

(5) Employee Stock-Based Compensation Arrangements

For all periods presented in the accompanying unaudited consolidated financial statements, we accounted for our employee stock-based compensation arrangements using the intrinsic value method under the provisions of Accounting Principles Board (APB) Opinion No. 25, *Accounting for Stock Issued to Employees*, and in accordance with Financial Accounting Standards Board (FASB) Interpretation (FIN) No. 44,

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

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(in thousands, except per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004 (restated)	2005	2004 (restated)
Net income (loss) as reported	\$ 2,503	\$ (6,733)	\$ (5,299)	\$ (10,116)
Stock-based employee compensation as reported	140		140	
Pro forma stock-based employee compensation	(1,387)	(1,203)	(2,973)	(2,805)
Net income (loss) pro forma	\$ 1,256	\$ (7,936)	\$ (8,132)	\$ (12,921)
Income (loss) per share basic:				
Net income (loss) per share as reported	\$ 0.11	\$ (0.34)	\$ (0.24)	\$ (0.56)
Stock-based employee compensation as reported	0.00		0.00	
Pro forma stock-based employee compensation	(0.06)	(0.06)	(0.13)	(0.14)
Net income (loss) per share pro forma	\$ 0.05	\$ (0.40)	\$ (0.37)	\$ (0.70)
Income (loss) per share diluted:				
Net income (loss) per share as reported	\$ 0.10	\$ (0.34)	\$ (0.24)	\$ (0.56)
Stock-based employee compensation as reported	0.00		0.00	
Pro forma stock-based employee compensation	(0.05)	(0.06)	(0.13)	(0.14)
Net income (loss) per share pro forma	\$ 0.05	\$ (0.40)	\$ (0.37)	\$ (0.70)

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 June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Risk-free interest rate	3.78-4.09%	2.87-3.95%	3.58-4.09%	2.8-3.95%
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 June 30, 2005 and 2004 was \$12.00 and \$9.01, respectively. The weighted average fair value under the Black-Scholes option pricing model of options granted to employees during the six months ended June 30, 2005 and 2004 was \$11.92 and \$9.19, respectively.

(6) 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 June 30,		Six Months Ended June 30,	
	2005	2004 (restated)	2005	2004 (restated)
Numerator:				
Net income (loss)	\$ 2,503	\$ (6,733)	\$ (5,299)	\$ (10,116)

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Dividends, redemption interest and amortization of beneficial conversion feature related to Series A Preferred Stock (749)

Net income (loss) available to common stockholders basic and diluted \$ 2,503 \$ (6,733) \$ (5,299) \$ (10,865)

Denominator:

Denominator for basic income (loss) per share weighted average shares 23,127 19,701 22,040 19,568

Effect of dilutive securities:

Employee stock options 1,113

Warrants 283

Restricted stock and escrow shares 104

Dilutive potential common shares 1,500

Denominator for dilutive income (loss) per share adjusted weighted average shares and assumed conversions 24,627 19,701 22,040 19,568

Net income (loss) per share - basic \$ 0.11 \$ (0.34) \$ (0.24) \$ (0.56)

Net income (loss) per share - diluted \$ 0.10 \$ (0.34) \$ (0.24) \$ (0.56)

We had the following potential dilutive securities outstanding on June 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 \$17.79 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 six months ended June 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 June 30, 2004: (a) options and warrants to purchase an aggregate of 4.2 million shares of common stock at a weighted average exercise price of \$15.90 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 six months ended June 30, 2004 because the effect of including the number of such potential dilutive securities would be antidilutive.

(7) Comprehensive Income (loss)

Comprehensive income or loss represents net income (loss) plus other comprehensive income (loss) items. Our other comprehensive income(loss) includes primarily foreign currency translation adjustments. For the three and six months ended June 30, 2005, we generated a comprehensive loss of \$1.1 million and \$11.4 million, respectively, and for the three and six months ended June 30, 2004, we generated comprehensive loss of \$7.2 million and \$10.3 million, respectively.

(8) Business Combinations

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

(a) Acquisition of 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 \$57.9 million, which consisted of \$56.5 million in cash and \$1.4 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:

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	(in thousands)	
Inventories	\$	500
Property, plant and equipment		1,500
Goodwill		34,883
Acquired intangibles		21,000
	\$	57,883

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.

The acquisition of the Determine Business is accounted for as a purchase under SFAS No. 141, *Business Combinations*.

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.

(b) *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		19,155
Core technology and intangible assets		15,000
Other assets		539
Deferred tax asset		6,000
Accounts payable and accrued expenses		(2,300)
Deferred tax liability		(6,000)
	\$	44,721

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 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.

(c) *Acquisition of Ischemia*

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

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

(in thousands)	
Cash and cash equivalents	\$ 115
Accounts receivable	58
Inventories	40
Property, plant and equipment	288
Goodwill	3,029
Core technology and patents	24,000
Other assets	99
Deferred tax asset	9,600
Accounts payable and accrued expenses	(377)
Deferred tax liability	(9,600)
	\$ 27,252

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

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

(d) 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.

(e) Pro Forma Financial Information

The following table presents selected unaudited financial information of our company, including Binax, Ischemia and the Determine Business, 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 consummated on January 1, 2004.

(in thousands, except per share amounts)	Three Months Ended June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004

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		(restated)		(restated)
Pro forma net revenues	\$ 107,841	\$ 98,091	\$ 214,697	\$ 200,761
Pro forma net income (loss)	\$ 2,522	\$ (9,026)	\$ (2,255)	\$ (12,465)
Pro forma net income (loss) available to common stockholders basic and diluted	\$ 2,522	\$ (9,026)	\$ (2,255)	\$ (13,214)
Pro forma net income (loss) per common share basic	\$ 0.11	\$ (0.41)	\$ (0.10)	\$ (0.61)
Pro forma net income (loss) per common share diluted	\$ 0.10	\$ (0.41)	\$ (0.10)	\$ (0.61)

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

(f) 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 June 30, 2005
Ischemia	\$	\$ 1,690	\$ (1,244)	\$	\$ 446
Ostex	910		(100)		810
IMN	263		(118)		145
Unipath business	1,453			(87)	1,366
Total restructuring costs	\$ 2,626	\$ 1,690	\$ (1,462)	\$ (87)	\$ 2,767

(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 \$1.2 million has been paid as of June 30, 2005. We estimated costs to vacate the Ischemia facilities to be approximately \$0.1 million, none of which has been paid as of June 30, 2005. We expect to pay the remaining costs during the remainder of 2005. The total number of involuntarily terminated employees was 17, of whom 16 were terminated as of June 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 June 30, 2005. Total severance costs associated with involuntarily terminated employees are \$1.6 million, of which all have been paid as of June 30, 2005. Costs to vacate the Ostex facilities are \$0.5 million, of which \$0.2 million has been paid as of June 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 June 30, 2005. Total unpaid exit costs amounted to \$0.8 million as of June 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 June 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 June 30, 2005, \$1.4 million, adjusted for foreign exchange effect, in exit costs remained unpaid.

(9) Restructuring Plan

On May 9, 2005, we committed to a plan to cease operations at our facility in Galway, Ireland. During the three and six months 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. The total restructuring charge, which consisted of \$2.9 million charged to cost of goods sold, \$0.4 million charged to research and development and \$0.2 million charged to general and administrative was included in our consumer products business segment. The total number of employees to be involuntarily terminated is 110. As of June 30, 2005, all restructuring costs remained unpaid. 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 \$1.2 million and \$1.6 million expected to be recorded in the third and fourth quarter of 2005.

(10) 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 \$54.2 million at June 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 \$67.7 million at June 30, 2005) in the programs over the next three years. Through our subsidiary, Stirling Medical Innovations Limited (Stirling), we intend to establish a new research center in Stirling, Scotland, where we will consolidate many of our existing cardiology programs and ultimately commercialize products arising from the programs. ITI and Stirling will have exclusive rights to the developed technology in their respective fields of use. As of June 30, 2005, we had received approximately \$13.9 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 six months ended June 30, 2005, we recognized \$7.0 million and \$9.4 million of reimbursements, respectively, of which \$6.9 million and \$8.8 million, respectively offset our research and development spending and \$0.1 million and \$0.6 million, respectively reduced our general, administrative and marketing spending incurred by Stirling, for the three and six months ended June 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 \$4.4 million as of June 30, 2005.

(11) 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. We have subsequently repaid the term loans and all but \$5.0 million of the funds borrowed under the revolving facility with the private placement discussed in Note 16 below.

(12) 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 June 30,		Six Months Ended June 30,	
	2005	2004	2005	2004
Service cost	\$ 66	\$ 446	\$ 134	\$ 900
Interest cost	149	51	303	103
Expected return on plan assets	(88)	(45)	(179)	(91)
Realized gains	11	5	22	11
Net periodic benefit costs	\$ 138	\$ 457	\$ 280	\$ 923

(13) 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 six months ended June 30, 2005, the latter of which amounted to \$1.9 million, net of the ITI funding of \$6.9 million (Note 9) and \$6.3 million, net of \$8.8 million of the ITI funding, respectively, and \$4.6 million and \$8.2 million for the three and six months ended June 30, 2005 and 2004, respectively. Total assets in the area of cardiology, which are included in Corporate and Other in the tables below, amounted to \$55.0 million at June 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 six months ended June 30, 2005 and 2004 is as follows:

(in thousands)	Consumer Diagnostic Products	Vitamins and Nutritional Supplements	Professional Diagnostic Products	Corporate And Other	Total
<u>Three Months Ended June 30, 2005</u>					
Net revenue from external customers	\$ 42,795	\$ 18,918	\$ 40,518	\$ 40	\$ 102,271
Operating income (loss)	6,102	(1,291)	(3,104)	(6,262)	(4,555)
<u>Three Months Ended June 30, 2004(restated)</u>					
Net revenue from external customers	\$ 37,821	\$ 18,534	\$ 32,788	\$	\$ 89,143
Operating income (loss)	8,899	(567)	2,263	(11,057)	(462)
<u>Six Months Ended June 30, 2005</u>					
Net revenue from external customers	\$ 86,215	\$ 35,839	\$ 72,028	\$ 109	\$ 194,191
Operating income (loss)	13,043	(3,151)	(5,590)	(15,045)	(10,743)
<u>Six Months Ended June 30, 2004(restated)</u>					
Net revenue from external customers	\$ 78,240	\$ 38,824	\$ 63,187	\$	\$ 180,251
Operating income (loss)	12,479	(597)	5,914	(14,155)	3,641
<u>At June 30, 2005</u>					
Assets	\$ 233,416	\$ 52,302	\$ 369,473	\$ 61,197	\$ 716,388
<u>At December 31, 2004(restated)</u>					
Assets	\$ 243,001	\$ 48,072	\$ 264,260	\$ 12,936	\$ 568,269

(14) Material Contingencies, Settlements and Other Arrangements

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

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

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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 three and six months ended June 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 three and six months ended June 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 June 30, 2005, an arbitrator issued an interim award against our IMN subsidiary in favor of Sunlight Distribution, Inc. for damages in the amount of \$1.8 million arising out of a distribution arrangement dated September 1996. The arbitrator has not yet rendered a final determination regarding the allocation of attorneys' fees and costs and the calculation of pre-award interest. We have accrued \$2.7 million as of June 30, 2005 to provide for the interim award and estimated fees, costs and interest due. The corresponding expense was recorded in other income, net, for the three and six months ended June 30, 2005.

(15) 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.

(16) Subsequent Event

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. After the repayment, we had outstanding borrowings under the revolving portion of the Senior Credit Facility of \$5.0 million, with an additional \$75.0 million of capacity available subject to continued covenant compliance. The repayment of the term loan balance will result in a non-cash write off of deferred financing costs of \$0.4 million in the third quarter of 2005.

(17) 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 six months ended June 30, 2005 and 2004 and the balance sheets as of June 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 parties.

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

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF OPERATIONS

For the Three Months Ended June 30, 2005

(in thousands)

(unaudited)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	\$ 6,498	\$ 58,444	\$ 48,736	\$ (15,905)	\$ 97,773
License revenue		95	4,403		4,498
Net revenue	6,498	58,539	53,139	(15,905)	102,271
Cost of sales	6,768	48,950	28,638	(16,798)	67,558
Gross profit	(270)	9,589	24,501	893	34,713
Operating expenses:					
Research and development	628	1,502	3,230		5,360
Sales and marketing	772	8,935	7,959		17,666
General and administrative	3,141	5,595	7,506		16,242
Total operating expenses	4,541	16,032	18,695		39,268
Operating (loss) income	(4,811)	(6,443)	5,806	893	(4,555)
Equity in earnings of subsidiaries, net of tax	10,745			(10,745)	
Interest expense, including amortization of discounts and write off of deferred financing costs	(4,080)	(327)	(1,505)	952	(4,960)
Other income (expense), net	512	(2,520)	17,832	(952)	14,872
Income (loss) before income taxes	2,366	(9,290)	22,133	(9,852)	5,357
Income tax (benefit) provision	(137)	418	2,533	40	2,854
Net income (loss)	\$ 2,503	\$ (9,708)	\$ 19,600	\$ (9,892)	\$ 2,503

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF OPERATIONS

For the Six Months Ended June 30, 2005

(in thousands)

(unaudited)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	\$ 11,976	\$ 109,530	\$ 94,078	\$ (28,112)	\$ 187,472
License revenue		126	6,593		6,719
Net revenue	11,976	109,656	100,671	(28,112)	194,191
Cost of sales	12,385	91,998	53,205	(30,299)	127,289
Gross profit	(409)	17,658	47,466	2,187	66,902
Operating expenses:					
Research and development	770	2,617	9,205		12,592
Sales and marketing	1,252	16,112	17,332		34,696
General and administrative	6,449	9,217	14,691		30,357
Total operating expenses	8,471	27,946	41,228		77,645
Operating (loss) income	(8,880)	(10,288)	6,238	2,187	(10,743)
Equity in earnings of subsidiaries, net of tax	14,653			(14,653)	
Interest expense, including amortization of discounts and write off of deferred financing costs	(8,324)	(811)	(2,848)	2,011	(9,972)
Other (expense) income, net	(2,563)	6,140	18,156	(1,950)	19,783
(Loss) income before income taxes	(5,114)	(4,959)	21,546	(12,405)	(932)
Income tax provision	185	1,136	3,046		4,367
Net (loss) income	\$ (5,299)	\$ (6,095)	\$ 18,500	\$ (12,405)	\$ (5,299)

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF OPERATIONS

For the Three Months Ended June 30, 2004

(restated)

(in thousands)

(unaudited)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	\$ 5,154	\$ 51,406	\$ 40,250	\$ (9,664)	\$ 87,146
License revenue		24	1,973		1,997
Net revenue	5,154	51,430	42,223	(9,664)	89,143
Cost of sales	4,723	40,028	19,978	(10,914)	53,815
Gross profit	431	11,402	22,245	1,250	35,328
Operating expenses:					
Research and development	4	887	7,101		7,992
Sales and marketing	546	6,582	6,533		13,661
General and administrative	3,212	4,936	5,989		14,137
Total operating expenses	3,762	12,405	19,623		35,790
Operating (loss) income	(3,331)	(1,003)	2,622	1,250	(462)
Equity in earnings of subsidiaries, net of tax	596			(596)	
Interest expense, including amortization of discounts and write off of deferred financing costs	(3,814)	(619)	(1,070)	962	(4,541)
Other income (expense), net	998	50	(57)	(962)	29
(Loss) income before income taxes	(5,551)	(1,572)	1,495	654	(4,974)
Income tax provision (benefit)	1,182	840	(263)		1,759
Net (loss) income	\$ (6,733)	\$ (2,412)	\$ 1,758	\$ 654	\$ (6,733)

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF OPERATIONS

For the Six Months Ended June 30, 2004

(restated)

(in thousands)

(unaudited)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	\$ 9,929	\$ 101,887	\$ 84,448	\$ (20,510)	\$ 175,754
License revenue		46	4,451		4,497
Net revenue	9,929	101,933	88,899	(20,510)	180,251
Cost of sales	9,767	78,442	41,754	(22,237)	107,726
Gross profit	162	23,491	47,145	1,727	72,525
Operating expenses:					
Research and development	100	1,515	13,800		15,415
Sales and marketing	1,017	13,179	13,816		28,012
General and administrative	5,527	8,480	11,450		25,457
Total operating expenses	6,644	23,174	39,066		68,884
Operating (loss) income	(6,482)	317	8,079	1,727	3,641
Equity in earnings of subsidiaries, net of tax	1,848			(1,848)	
Interest expense, including amortization of discounts and write off of deferred financing costs	(6,987)	(4,553)	(2,374)	1,603	(12,311)
Other income, net	1,729	200	150	(1,603)	476
(Loss) income before income taxes	(9,892)	(4,036)	5,855	(121)	(8,194)
Income tax provision	224	1,025	673		1,922
Net (loss) income	\$ (10,116)	\$ (5,061)	\$ 5,182	\$ (121)	\$ (10,116)

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING BALANCE SHEET

June 30, 2005

(in thousands)

(unaudited)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
ASSETS					
Current Assets:					
Cash and cash equivalents	\$ 345	\$ 9,697	\$ 18,844	\$	\$ 28,886
Accounts receivable, net of allowances	1,691	29,560	19,877		51,128
Inventories	5,754	42,751	21,349	(3,825)	66,029
Deferred tax assets		142	2,819		2,961
Prepaid expenses and other current assets	1,995	2,691	9,577		14,263
Intercompany receivables	61,805	65,534	27,551	(154,890)	
Total current assets	71,590	150,375	100,017	(158,715)	163,267
Property, plant and equipment, net	2,839	30,377	34,818		68,034
Goodwill	41,224	109,116	127,857		278,197
Other intangible assets with indefinite lives	5,000	12,420	47,685		65,105
Core technology and patents, net	30,702	5,834	31,136		67,672
Other intangible assets, net	4,821	19,376	20,881		45,078
Deferred financing costs, net, and other non-current assets	6,553	2,159	4,061		12,773
Deferred tax assets	15,600		617	45	16,262
Investment in subsidiaries	280,963	(1,113)		(279,850)	
Intercompany notes receivable	98,406	1,266	1	(99,673)	
Total assets	\$ 557,698	\$ 329,810	\$ 367,073	\$ (538,193)	\$ 716,388
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Current portion of long-term debt	\$	\$	\$ 359	\$	\$ 359
Current portion of capital lease obligations		497	5		502
Accounts payable	2,704	20,398	11,767		34,869
Accrued expenses and other current liabilities	13,817	24,886	28,038		66,741
Intercompany payables	34,249	25,304	95,337	(154,890)	
Total current liabilities	50,770	71,085	135,506	(154,890)	102,471
Long-term liabilities:					
Long-term debt, net of current portion	169,356	50,000	39,076		258,432
Capital lease obligations, net of current portion		1,180			1,180
Deferred tax liabilities	17,176	4,927	6,989		29,092
Other long-term liabilities		29	4,826		4,855

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Intercompany notes payable	38	49,896	49,739	(99,673)	
Total long-term liabilities	186,570	106,032	100,630	(99,673)	293,559
Stockholders equity	320,358	152,693	130,937	(283,630)	320,358
Total liabilities and stockholders equity	\$ 557,698	\$ 329,810	\$ 367,073	\$ (538,193)	\$ 716,388

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING BALANCE SHEET

December 31, 2004

(restated)

(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

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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 Six Months Ended June 30, 2005

(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Operating Activities:					
Net (loss) income	\$ (5,299)	\$ (6,095)	\$ 18,500	\$ (12,405)	\$ (5,299)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:					
Equity in earnings of subsidiaries, net of tax	(14,653)			14,653	
Interest expense related to amortization and/or write-off of non-cash original issue discount, and deferred financing costs	589	196	114		899
Noncash stock-based compensation	140				140
Depreciation and amortization	1,419	4,590	6,676		12,685
Deferred income taxes	224	1,052			1,276
Other noncash items	733	(10)	(129)		594
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net	969	12,067	1,371		14,407
Inventories	586	1,527	(2,173)	(2,248)	(2,308)
Prepaid expenses and other current assets	(717)	(513)	(4,399)		(5,629)
Accounts payable	1,027	(1,251)	588		364
Accrued expenses and other current liabilities	387	2,871	8,388		11,646
Increase in other long-term liabilities			433		433
Intercompany payable (receivable)	12,697	5,454	(18,570)	419	
Net cash (used in) provided by operating activities	(1,898)	19,888	10,799	419	29,208

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Investing Activities:					
Purchases of property, plant and equipment	(428)	(3,496)	(5,211)		(9,135)
Proceeds from sale of property, plant and equipment		69	82		151
Payments for acquisitions	(14,896)	1,671	(61,471)		(74,696)
Decrease (increase) in other assets	117	(52)	(853)		(788)
Net cash used in investing activities	(15,207)	(1,808)	(67,453)		(84,468)
Cash Flows from Financing Activities:					
Cash paid for financing costs	(707)	(702)	(649)		(2,058)
Proceeds from issuance of common stock, net of issuance costs	2,222				2,222
Net repayment under revolving lines of credit	(77)	20,000	29,249		49,172
Repayments of notes payable		10,000	10,086		20,086
Principal payments of capital lease obligations		(233)	(4)		(237)
Intercompany notes payable (receivable)	16,000	(41,000)	25,000		
Net cash provided by (used in) financing activities	17,438	(11,935)	63,682		69,185
Foreign exchange effect on cash and cash equivalents		1	(1,377)	(419)	(1,795)
Net increase in cash and cash equivalents	333	6,146	5,651		12,130
Cash and cash equivalents, beginning of period	12	3,551	13,193		16,756
Cash and cash equivalents, end of period	\$ 345	\$ 9,697	\$ 18,844	\$	\$ 28,886

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF CASH FLOWS

For the Six Months Ended June 30, 2004

(restated)

(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Operating Activities:					
Net (loss) income	\$ (10,116)	\$ (5,061)	\$ 5,182	\$ (121)	\$ (10,116)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:					
Equity in earnings of subsidiaries, net of tax	(1,848)			1,848	
Interest expense related to amortization and/or write-off of non-cash original issue discount, and deferred financing costs	548	3,068	344		3,960
Noncash gain related to interest rate swap agreement	(434)				(434)
Depreciation and amortization	818	4,086	6,475		11,379
Deferred income taxes	224	1,058			1,282
Other noncash items		(46)	(33)		(79)
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net	1,852	2,639	(1,922)		2,569
Inventories	(1,068)	(202)	(3,451)	(1,727)	(6,448)
Prepaid expenses and other current assets	(403)	(150)	1,983		1,430
Intercompany payables or receivables	1,095	(164)	(1,088)	157	
Accounts payable	(3,666)	(428)	(2,414)		(6,508)
Accrued expenses and other current liabilities	6,550	(1,797)	3,958		8,711
Increase in other long-term liabilities		29	273		302
Net cash (used in) provided by operating activities	(6,448)	3,032	9,307	157	6,048

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Investing Activities:					
Purchases of property, plant and equipment	(1,383)	(3,115)	(5,427)		(9,925)
Proceeds from sale of property, plant and equipment		123	59		182
Payments for acquisitions	(4,633)	(926)	(2,927)		(8,486)
(Increase) decrease in other assets	(759)	228	(263)		(794)
Net cash used in investing activities	(6,775)	(3,690)	(8,558)		(19,023)
Cash Flows from Financing Activities:					
Cash paid for financing costs	(4,764)	(325)	(28)		(5,117)
Proceeds from issuance of common stock, net of issuance costs	546				546
Proceeds from issuance of senior subordinated notes	150,000				150,000
Net repayment under revolving lines of credit		(16,680)	(23,278)		(39,958)
Repayments of notes payable	(9,000)	(75,533)	(9,972)		(94,505)
Principal payments of capital lease obligations		(241)	(1)		(242)
Intercompany notes (receivable) payable	(124,809)	91,949	32,860		
Net cash provided by (used in) financing activities	11,973	(830)	(419)		10,724
Foreign exchange effect on cash and cash equivalents			(219)	(157)	(376)
Net (decrease) increase in cash and cash equivalents	(1,250)	(1,488)	111		(2,627)
Cash and cash equivalents, beginning of period	1,708	11,315	11,599		24,622
Cash and cash equivalents, end of period	\$ 458	\$ 9,827	\$ 11,710	\$	\$ 21,995

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, benefits to be realized as a result of synergies relating to our acquisitions, our funding plans for our future working capital needs and commitments, and the impact of our acquisitions. Actual results or developments could differ materially from those projected in such statements as a result of numerous factors, including, without limitation, those risks and uncertainties set forth below under **Certain Factors Affecting Future Results** and **Special Statement Regarding Forward-Looking Statements**. The following discussion and analysis of our financial condition and results of operations should be read in light of those risks and uncertainties and in conjunction with our accompanying consolidated financial statements and notes thereto.

Restatement

On June 28, 2005, we announced that certain of our previously issued financial statements must be restated because they contain errors under accounting principles generally accepted in the United States (GAAP) relating to the recognition of revenue at one of our diagnostic divisions. We had determined that certain customers of this division were provided return or exchange rights in connection with the sale of products, as a result of which the revenues associated with these sales should not have been recognized upon shipment to the customers under GAAP. Since that time the Audit Committee of our Board of Directors conducted an investigation into these matters using independent special counsel. The results of this investigation contributed to our determination that the necessary restatement required \$4.2 million in net revenue reversal with a \$3.1 million gross margin and corresponding net loss impact spread over the quarters of 2003 and 2004 and the first quarter of 2005. In addition, we have taken an inventory write off of \$2.4 million related to excess quantities of raw material and finished goods for product at the diagnostic division, which is recorded as a cost of sales in the second quarter of 2005.

Our financial statements included in this quarterly report on Form 10-Q reflect the results of the matters discussed above. In addition, we intend to restate our audited financial statements for the fiscal years ended December 31, 2004 and December 31, 2003 included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2004, as well as our unaudited financial statements for the periods ended September 30, 2004 and September 30, 2003 included in Amendment No. 1 to our Quarterly Report on Form 10-Q/A for the period ended September 30, 2004, and our unaudited financial statements for the periods ended March 31, 2005 and March 31, 2004 included in our Quarterly Report on Form 10-Q for the period ended March 31, 2005.

Financial Overview

For the three and six months ended June 30, 2005, we recorded net revenue of \$102.3 million and \$194.2 million, respectively, compared to net revenue of \$89.1 million and \$180.3 million for the three and six months ended June 30, 2004, respectively. Adjusted for the impact of currency translation, net revenue for the three and six months ended June 30, 2005 was \$101.6 million and \$192.4 million, respectively. Overall revenue growth for the six months ended June 30, 2005, adjusted for the impact of currency translation, resulted from acquisitions principally in our professional diagnostics business and, to a lesser extent, organic growth, which occurred primarily in our consumer diagnostics business. Our

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acquisitions in the second half of 2004 and first half of 2005, contributed approximately 82% of our currency adjusted revenue growth for the six months ended June 30, 2005.

For the three and six months ended June 30, 2005, we recorded net income of \$2.5 million and a net loss of \$5.3 million, respectively, compared to a net loss of \$6.7 million and \$10.1 million for the three and six months ended June 30, 2004, respectively. Factors that contributed to the lower loss in 2005 through June, as compared to the loss in the comparable period of 2004, include (i) a \$3.5 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, (iii) higher interest expense due to higher average debt balance and weighted average interest rate primarily resulting from our decision to refinance our debt in February 2004, and (iv) 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 offset by net settlement and litigation gains totaling \$19.1 million.

As a leading global developer of advanced diagnostic devices, we are continually exploring opportunities in a variety of professional diagnostic and consumer-oriented applications, including immuno-diagnostics with a focus on women's health, cardiology and infectious disease. Our emphasis on new product development requires substantial investment and involves significant inherent risk. We intend to continue to devote substantial resources to research and development activities. Our recently announced co-development agreement with ITI Scotland Ltd., or ITI Scotland, who will provide us with 30 million pounds 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 increased gross margins of 166 basis points 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 product transition is currently underway and is anticipated to be completed in the third quarter of 2005 for all countries except Japan, where the transition will occur in 2006. 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 of 64 basis points 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 \$13.2 million, or 15%, to \$102.3 million for the three months ended June 30, 2005 from \$89.1 million for the three months ended June 30, 2004. Net revenue increased by \$13.8 million, or 8%, to \$194.2 million for the six months ended June 30, 2005 from \$180.3 million for the six months ended June 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 \$10.7 million, or 12%, to \$97.8 million for the three months ended June 30, 2005 from \$87.1 million for the three months ended June 30, 2004. Net product sales increased by \$11.7 million, or 7%, to \$187.5 million for the six months ended June 30, 2005 from \$175.8 million for the six months ended June 30, 2004. Adjusted for the favorable impact of currency translation on our foreign operations, total net product sales in the three and six months ended June 30, 2005 grew by approximately \$10.0 million, or 11%, and \$9.9 million, or 6%, respectively, compared to the same periods in 2004.

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

(in thousands)	Three Months ended June 30,			Six Months ended June 30,			% Increase (Decrease)
	2005	2004 (restated)	%	2005	2004 (restated)	%	
Consumer diagnostic products	\$ 41,992	\$ 36,475	15%	\$ 83,927	\$ 75,225	12%	
Vitamins and nutritional supplements	18,918	18,534	2%	35,839	38,824	(8)%	
Professional diagnostic products	36,863	32,137	15%	67,706	61,705	10%	
Total net product sales	\$ 97,773	\$ 87,146	12%	\$ 187,472	\$ 175,754	7%	

Adjusted for currency translation impact, net product sales of our consumer diagnostic products increased by \$5.1 million, or 14%, comparing the three months ended June 30, 2005 to the three months ended June 30, 2004 and \$7.5 million, or 10%, comparing the six months ended June 30, 2005 to the six months ended June 30, 2004. The increase in each period represents organic growth in our premium pregnancy test products and \$0.5 million and \$0.9 million of sales contributed from our acquisition of ACS in January 2005.

Our vitamins and nutritional supplements business grew by \$0.4 million, or 2%, comparing the three months ended June 30, 2005 to the three months ended June 30, 2004 and declined by \$3.0 million, or 8%, comparing the six months ended June 30, 2005 to the six months ended June 30, 2004. Sales decreased by \$1.3 million and \$3.0 million comparing the three and six months ended June 30, 2005 to the three and six months ended June 30, 2004, respectively, 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 three months ended June 30, 2005 was offset by a \$1.3 million increase in contract manufacturing sales to third party nutritional suppliers. The remaining decrease in net product sales of our vitamins and nutritional supplements business during the first six months of 2005 resulted from competition due to continued excess capacity in the industry.

Adjusted for currency translation impact, net product sales of our professional diagnostic products increased by \$4.5 million, or 14%, comparing the three months ended June 30, 2005 to the three months ended June 30, 2004 and increased by \$5.5 million, or 9%, comparing the six months ended June 30, 2005 to the six months ended June 30, 2004. Our acquisition of Binax in March 2005, contributed \$4.8 million of net product sales of our professional diagnostic products for the three and six month periods ended June 30, 2005. Viva Diagnostika, or Viva, acquired in June 2004, contributed \$2.2 and \$4.8 million of net product sales for the three and six month periods ended June 30, 2005 compared to \$0.5 million for the three and six month periods ended June 30, 2004. Excluding the impact from currency translation and acquisitions, net product sales of our professional diagnostic products decreased by \$1.6 million and \$3.3 million, comparing the three and six month periods ended June 30, 2005 to the three month and six month periods ended June 30, 2004. The decline in sales of our professional diagnostic products primarily resulted from decreased sales of certain of our drugs of abuse diagnostic products due to an FDA issue at our subsidiary Applied Biotech, Inc., or ABI. See detailed discussion of the FDA issue at ABI in the risk factor entitled "Our failure to meet strict regulatory requirements could require us to pay fines, incur other costs or even close our facilities" in the section entitled "Certain Factors Affecting Future Results" included herein. In addition, during the first quarter of 2005, we recorded a \$0.3 million specific returns reserve, which reduced our net product sales, due to a recall of two of our drugs of abuse diagnostic products following our decision to withdraw the products 510(k)s. The products impacted by the recall contributed approximately 1% of our consolidated net revenues in 2004. We believe that our recently executed joint venture agreement with PBM related to drugs of abuse diagnostic products should to a great extent replace these recalled products.

License Revenue. License revenue represents license and royalty fees from intellectual property license agreements with third-parties. License revenue increased by \$2.5 million, or 125%, to \$4.5 million for the three months ended June 30, 2005 from \$2.0 million for the three months ended June 30, 2004 and by \$2.2 million, or 49%, to \$6.7 million for the six months ended June 30, 2005 from \$4.5 million for the six months ended June 30, 2004. The increase for both the

three and six month periods primarily relating to the royalty revenues from Quidel.

Gross Profit and Margin. Gross profit decreased by \$0.6 million, or 2%, to \$34.7 million for the three months ended June 30, 2005 from \$35.3 million for the three months ended June 30, 2004. Gross profit decreased by \$5.6 million, or 8%, to \$66.9 million for the six months ended June 30, 2005 from \$72.5 million for the six months ended June 30, 2004. The gross profit decrease, comparing the three and six months ended June 30, 2005 to the three and six months ended June 30, 2004, resulted from: (i) the inclusion in cost of sales in the three month period ended June 30, 2005 of a \$2.9 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. Gross profit from our nutritional supplements business principally the private label business, declined by \$0.4 million and \$1.8 million, comparing the three and six months ended June 30, 2005 to the three and six months ended June 30, 2004. Our private label nutritional supplements business has suffered from excess capacity in the industry which led to increasing price competition. Offsetting these decreases was the gross profit earned through the organic growth in our net consumer product sales, the gross profit contributed from businesses acquired and the gross profit earned on increased license revenues.

Overall gross margin was 34% for the three and six months ended June 30, 2005 compared to 40% for the three and six months ended June 30, 2004, respectively. Overall gross margin in 2005 was adversely affected by the \$2.9 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 39% and 38% for the three and six month periods ended June 30, 2005, respectively.

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 decreased by \$2.9 million, or 8%, to \$31.3 million for the three months ended June 30, 2005 from \$34.2 million for the three months ended June 30, 2004. Gross profit from total net product sales decreased by \$7.5 million, or 11%, to \$62.2 million for the six months ended June 30, 2005 from \$69.7 million for the six months ended June 30, 2004.

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

(in thousands)	Three Months ended June 30,			% Increase (Decrease)	Six Months ended June 30,			% Increase (Decrease)
	2005	2004 (restated)			2005	2004 (restated)		
Consumer diagnostic products	\$ 18,548	\$ 19,354	(4)%	\$ 39,472	\$ 40,630	(3)%		
Vitamins and nutritional supplements	1,238	2,104	(41)%	1,927	4,729	(59)%		
Professional diagnostic products	11,493	12,715	(10)%	20,844	24,328	(14)%		