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)

ý 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

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

for the transition period from to

COMMISSION FILE NUMBER 001-16789

INVERNESS MEDICAL INNOVATIONS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

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

51 SAWYER ROAD, SUITE 200

WALTHAM, MASSACHUSETTS 02453

(Address of principal executive offices)

(781) 647-3900

(Registrant s Telephone Number, Including Area Code)

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

Yes ý No o

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

Yes ý No o

The number of shares outstanding of the registrant s common stock as of 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

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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)

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.

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 basic 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,

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:

(in thousands, except per share amounts)	Three Months Ended June 30, 2005	Three Months Ended June 30, 2004 (restated)	Six Months Ended June 30, 2005	Six Months Ended June 30, 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, 2005	Three Months Ended June 30, 2004	Six Months Ended June 30, 2005	Six Months Ended June 30, 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, 2005	Three Months Ended June 30, 2004 (restated)	Six Months Ended June 30, 2005	Six Months Ended June 30, 2004 (restated)
Numerator:				
Net income (loss)	$ 2,503	$ (6,733)	$ (5,299)	$ (10,116)

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:

		(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

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 consumated on January 1, 2004.

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

				(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:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	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
Three Months Ended June 30, 2005					
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)
Three Months Ended June 30, 2004(restated)					
Net revenue from external customers	$ 37,821	$ 18,534	$ 32,788	$	$ 89,143
Operating income (loss)	8,899	(567)	2,263	(11,057)	(462)
Six Months Ended June 30, 2005					
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)
Six Months Ended June 30, 2004(restated)					
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
At June 30, 2005					
Assets	$ 233,416	$ 52,302	$ 369,473	$ 61,197	$ 716,388