INVERNESS MEDICAL INNOVATIONS INC
Form 10-Q
May 10, 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 March 31, 2005

OR

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

for the transition period from to

COMMISSION FILE NUMBER 001-16789

INVERNESS MEDICAL INNOVATIONS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

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

51 SAWYER ROAD, SUITE 200

WALTHAM, MASSACHUSETTS 02453

(Address of principal executive offices)

(781) 647-3900

(Registrant s Telephone Number, Including Area Code)

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

Yes ý No o

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

Yes ý No o

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

INVERNESS MEDICAL INNOVATIONS, INC.

FORM 10-Q

For the Quarterly Period Ended March 31, 2005

This quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Readers can identify these statements by forward-looking words such as may, could, should, would, intend, will, expect, anticipate, believe, estimate, continue or similar words. There are important factors that could cause actual results of Inverness Medical Innovations, Inc. and its subsidiaries to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the risk factors detailed in this quarterly report on Form 10-Q and other risk factors identified from time to time in our periodic filings with the Securities and Exchange Commission. Readers should carefully review the factors discussed in the section entitled Management s Discussion and Analysis of Financial Condition and Results of Operations Certain Factors Affecting Future Results and Special Statement Regarding Forward-Looking Statements beginning on pages 33 and 45, respectively, in this quarterly report on Form 10-Q and should not place undue reliance on our forward-looking statements. These forward-looking statements are based on information, plans and estimates at the date of this report. We undertake no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes.

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

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PART I - **FINANCIAL INFORMATION**

ITEM 1. **FINANCIAL STATEMENTS**

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

(in thousands, except per share amounts)

	Three Months Ended March 31,	
	2005	**2004**
Net product sales	$ 89,391	$ 88,201
License revenue	2,221	2,500
Net revenue	91,612	90,701
Cost of sales	59,716	53,792
Gross profit	31,896	36,909
Operating expenses:		
Research and development (Note 8)	7,232	7,423
Sales and marketing	17,030	14,351
General and administrative	14,115	11,320
Total operating expenses	38,377	33,094
Operating (loss) income	(6,481)	3,815
Interest expense, including amortization of discounts and write-off of deferred financing costs	(5,012)	(7,770)
Other income, net	4,911	447
Loss before income taxes	(6,582)	(3,508)
Income tax provision	1,513	163
Net loss	$ (8,095)	$ (3,671)
Net loss available to common stockholders basic and diluted (Note 5)	$ (8,095)	$ (4,420)
Net loss per common share basic and diluted (Note 5)	$ (0.39)	$ (0.23)
Weighted average shares basic and diluted (Note 5)	20,942	19,216

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

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

(in thousands, except per share amounts)

	March 31, 2005	December 31, 2004
ASSETS		
Current assets:		
Cash and cash equivalents	$ 33,667	$ 16,756
Accounts receivable, net of allowances of $9,973 at March 31, 2005 and $9,359 at December 31, 2004	57,814	61,347
Inventories	65,437	60,143
Deferred tax assets	2,961	2,819
Prepaid expenses and other current assets	14,128	9,601
Total current assets	174,007	150,666
Property, plant and equipment, net	69,244	66,780
Goodwill	258,886	221,155
Other intangible assets with indefinite lives	55,356	50,542
Core technology and patents, net	68,540	40,327
Other intangible assets, net	35,445	27,680
Deferred financing costs, net, and other non-current assets	9,335	9,156
Deferred tax assets	794	872
Total assets	$ 671,607	$ 567,178
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 329	$ 88
Current portion of capital lease obligations	492	467
Accounts payable	39,471	32,345
Accrued expenses and other current liabilities	62,288	51,886
Total current liabilities	102,580	84,786
Long-term liabilities:		
Long-term debt, net of current portion	211,315	189,268
Capital lease obligations, net of current portion	1,312	1,401
Deferred tax liabilities	28,726	12,596
Other long-term liabilities	4,721	4,446
Total long-term liabilities	246,074	207,711
Commitments and contingencies		
Series A redeemable convertible preferred stock, $0.001 par value:		
Authorized 2,667 shares		
Issued 2,527 shares		
Outstanding none		
Stockholders equity:		
Preferred stock, $0.001 par value:		
Authorized 2,333 shares, none issued		
Common stock, $0.001 par value:		
Authorized 50,000 shares		
Issued and outstanding 23,191 at March 31, 2005 and 20,711 shares at December 31, 2004	23	21
Additional paid-in capital	418,440	359,582

Notes receivable from stockholders		(14,691)		(14,691)
Accumulated deficit		(95,847)		(87,752)
Accumulated other comprehensive income		15,028		17,521
Total stockholders equity		322,953		274,681
Total liabilities and stockholders equity	$	671,607	$	567,178

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

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

(in thousands)

	Three Months Ended March 31,	
	2005	**2004**
Cash Flows from Operating Activities:		
Net loss	$ (8,095)	$ (3,671)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Interest expense related to amortization and/or write-off of noncash original issue discount and deferred financing costs	443	3,311
Noncash charge related to interest rate swap agreement		64
Depreciation and amortization	6,202	5,575
Deferred income taxes	638	(701)
Other noncash items	(68)	(19)
Minority interest	207	
Changes in assets and liabilities, net of acquisitions:		
Accounts receivable, net	8,688	23
Inventories	(3,012)	(3,441)
Prepaid expenses and other current assets	(4,476)	596
Accounts payable	5,348	(5,820)
Accrued expenses and other current liabilities	9,356	2,370
Other non-current liabilities	76	
Net cash provided by (used in) operating activities	15,307	(1,713)
Cash Flows from Investing Activities:		
Purchases of property, plant and equipment	(3,979)	(4,401)
Proceeds from sale of property, plant and equipment	43	28
Payments for acquisitions and of transactional costs for previous acquisitions	(15,776)	(2,364)
Increase in other assets	(394)	(815)
Net cash used in investing activities	(20,106)	(7,552)
Cash Flows from Financing Activities:		
Cash paid for financing costs	(355)	(4,666)
Proceeds from issuance of common stock, net of issuance costs	899	521
Proceeds from issuance of senior subordinated notes		150,000
Net proceeds (repayment) under revolving line of credit	22,170	(40,460)
Repayments of notes payable	(9)	(94,241)
Principal payments of capital lease obligations	(115)	(107)
Net cash provided by financing activities	22,590	11,047
Foreign exchange effect on cash and cash equivalents	(880)	(262)
Net increase in cash and cash equivalents	16,911	1,520
Cash and cash equivalents, beginning of period	16,756	24,622
Cash and cash equivalents, end of period	$ 33,667	$ 26,142
Supplemental Disclosure of Noncash Activities:		
Dividends, redemption interest and amortization of beneficial conversion feature related to preferred stock	$	$ 749
Fair value of stock issued for acquisitions	$ 57,962	$
Conversion of preferred stock to common stock	$	$ 6,934

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

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(UNAUDITED)

(1) Basis of Presentation of Financial Information

The accompanying consolidated financial statements of Inverness Medical Innovations, Inc. and its subsidiaries are unaudited. In the opinion of management, the unaudited consolidated financial statements contain all adjustments considered normal and recurring and necessary for their fair presentation. Interim results are not necessarily indicative of results to be expected for the year. These interim financial statements have been prepared in accordance with the instructions for Form 10-Q and therefore do not include all information and footnotes necessary for a complete presentation of operations, financial position, and cash flows in conformity with accounting principles generally accepted in the United States of America (GAAP). Our audited consolidated financial statements for the year ended December 31, 2004 included information and footnotes necessary for such presentation and were included in our annual report on Form 10-K filed with the Securities and Exchange Commission on March 16, 2005. These unaudited consolidated financial statements should be read in conjunction with our audited consolidated financial statements and notes thereto for the year ended December 31, 2004.

(2) Cash and Cash Equivalents

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

(3) Inventories

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

(in thousands)	March 31, 2005	December 31, 2004
Raw materials	$ 25,866	$ 23,434
Work-in-process	16,419	14,956
Finished goods	23,152	21,753
	$ 65,437	$ 60,143

(4) Employee Stock-Based Compensation Arrangements

For all periods presented in the accompanying unaudited consolidated financial statements, we accounted for our employee stock-based compensation arrangements using the intrinsic value method under the provisions of Accounting Principles Board (APB) Opinion No. 25,

Accounting for Stock Issued to Employees, and in accordance with Financial Accounting Standards Board (FASB) Interpretation (FIN) No. 44, *Accounting for Certain Transactions Involving Stock Compensation*. We have elected to use the disclosure-only provisions of Statement of Financial Accounting Standards (SFAS) No. 123, *Accounting for Stock-Based Compensation*, and SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure.*

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

(in thousands, except per share amounts)	Three Months Ended March 31, 2005	2004
Net loss as reported	$ (8,095)	$ (3,671)
Pro forma stock-based employee compensation	(1,586)	(1,603)
Net loss pro forma	$ (9,681)	$ (5,274)
Loss per share basic and diluted:		
Net loss per share as reported	$ (0.39)	$ (0.23)
Pro forma stock-based employee compensation	(0.07)	(0.08)
Net loss per share pro forma	$ (0.46)	$ (0.31)

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

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

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

(5) Loss Per Share

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

(in thousands, except per share amounts)	Three Months Ended March 31, 2005	2004
Numerator:		
Net loss	$ (8,095)	$ (3,671)
Dividends, redemption interest and amortization of beneficial conversion feature related to Series A Preferred Stock		(749)
Net loss available to common stockholders basic and diluted	$ (8,095)	$ (4,420)
Denominator:		
Denominator for basic and diluted loss per share weighted average shares	20,942	19,216
Net loss per share basic and diluted	$ (0.39)	$ (0.23)

We had the following potential dilutive securities outstanding on March 31, 2005: (a) options and warrants to purchase an aggregate of 4.3 million shares of common stock at a weighted average exercise price of $16.58 per share, and (b) 104,000 shares of common stock held in escrow. These potential dilutive securities were not included in the computation of diluted loss per share because the effect of including such potential dilutive securities would be antidilutive.

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

(6) Comprehensive Income or Loss

Comprehensive income or loss represents net income or loss plus other comprehensive income or loss items. Our other comprehensive income or loss includes primarily foreign currency translation adjustments.. For the three months ended March 31, 2005 and 2004, we generated a comprehensive loss of $10.6 million and $3.3 million, respectively.

(7) Business Combinations

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

(a) Acquisition of Binax

On March 31, 2005, we acquired Binax, Inc (Binax), a privately held developer, manufacturer and distributor of rapid diagnostic products for infectious disease testing, primarily related to the respiratory system. The preliminary aggregate purchase price was $44.7 million which consisted of $9.0 million in cash, 1.4 million shares of our common stock with an aggregate fair value of $35.2 million and $0.5 million in estimated direct acquisition costs. The terms of the acquisition agreement also provide for $11.0 million of contingent cash consideration payable to the Binax shareholders upon the successful completion of certain new product developments during the next five years. This contingent consideration will be accounted for as an increase in the preliminary aggregate purchase price and goodwill if and when the contingency is met.

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

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

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

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

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

(b) Acquisition of Ischemia

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

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

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

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

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

(c) Acquisition of ACS

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

(d) Pro Forma Financial Information

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

(in thousands, except per share amounts)	Three Months Ended March 31, 2005	2004
Pro forma net revenue	$ 101,441	$ 97,463
Pro forma net loss	(5,996)	(3,378)
Net loss available to common stockholders basic and diluted (1)	(5,996)	(4,127)
Pro forma net loss per common share basic and diluted (1)	$ (0.26)	$ (0.19)

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

(e) Restructuring Plans of Acquisitions

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

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

(1) Represents foreign currency translation adjustment.

In connection with our acquisition of Ischemia in March 2005, we established a restructuring plan whereby we will exit the current facilities of Ischemia in Denver, Colorado, and combine its activities with our existing manufacturing and distribution facilities by mid-2005. Total severance costs associated with involuntarily terminated employees are estimated to be $1.6 million, of which $1.0 million has been paid as of March 31, 2005. We estimated costs to vacate the Ischemia facilities to be approximately $100,000, none of which has been paid as of March 31, 2005. The total number of involuntarily terminated employees was 17, of whom 7 were terminated as of March 31, 2005. Although

we believe our plan and estimated exit costs are reasonable, actual spending for exit activities may differ from current estimated exit costs, which might impact the final aggregate purchase price.

As a result of our acquisition of Ostex, we established a restructuring plan whereby we exited the facilities of Ostex in Seattle, Washington, and combined the activities of Ostex with our existing manufacturing and distribution facilities. The total number of employees to be terminated involuntarily under the restructuring plan is 38, of which all were terminated as of March 31, 2005. Total severance costs associated with involuntarily terminated employees are $1.6 million, of which all has been paid as of March 31, 2005. Costs to vacate the Ostex facilities are $0.5 million, of which $0.2 million has been paid as of March 31, 2005. Additionally, the remaining costs to exit operations, primarily facilities lease commitments, are $1.9 million, of which $1.4 million has been paid as of March 31, 2005. Total unpaid exit costs amounted to $0.8 million as of March 31, 2005.

Immediately after the close of the acquisition, we reorganized the business operations of IMN to improve efficiencies and eliminate redundant activities on a company-wide basis. The restructuring affected all cost centers within the organization, but most significantly responsibilities at the sales and executive levels, as such activities were combined with our existing business operations. Also as part of the restructuring plan, we relocated one of IMN s warehouses to a closer proximity of the manufacturing facility to improve efficiency. Of the $1.6 million in total exit costs, which include severance costs of 47 involuntarily terminated employees and costs to vacate the warehouse, $1.4 million has been paid and $0.2 million remains unpaid as of March 31, 2005.

As a result of the acquisition of the Unipath business from Unilever Plc in 2001, we reorganized the operations of the Unipath business for purposes of improving efficiencies and achieving economies of scale on a company-wide basis. Such reorganization affected all major cost centers at the operations in England. Additionally, most business activities of the U.S. division were merged into our existing U.S. businesses. Total exit costs, which primarily related to severance and early retirement obligations of 65 involuntarily terminated employees, were $4.1 million. As of March 31, 2005, $1.4 million, adjusted for foreign exchange effect, in exit costs remained unpaid.

(8) Co-Development Arrangement

On February 25, 2005, we entered into a co-development agreement with ITI Scotland Limited (ITI), whereby ITI agreed to provide us with approximately £30 million (or $56.5 million at March 31, 2005) over three years to partially fund research and development programs focused on identifying novel biomarkers and near-patient and home use tests for cardiovascular and other diseases (the Programs). We agreed to invest £37.5 million (or $70.6 million at March 31, 2005) in the programs over the next three years. Through our subsidiary, Stirling Medical Innovations Limited (Stirling), we intend to establish a new research center in Stirling, Scotland, where we will consolidate many of our existing cardiology programs and ultimately commercialize products arising from the programs. ITI and Stirling will have exclusive rights to the developed technology in their respective fields of use. As of March 31, 2005, we had received approximately $11 million in funding from ITI. As qualified expenditures are made under the co-development arrangement, we recognize the fee earned during the period as a reduction of our related expenses, subject to certain limitations. For the three months ended March 31, 2005, we recognized $2.2 million of reimbursements, of which $1.9 million offset our research and development spending and $0.3 million reduced our general and administrative spending incurred by Stirling. Funds received from ITI in excess of amounts earned are included in accrued expenses and other current liabilities, the balance of which was $7.1 million as of March 31, 2005.

(9) Defined Benefit Pension Plan

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

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

(10) Financial Information by Segment

Under SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision making group, in deciding how to allocate resources and in assessing performance. Our chief operating decision making group is composed of the chief executive officer and members of senior management. Our reportable operating segments are Consumer Diagnostic Products, Vitamins and Nutritional Supplements, Professional Diagnostic Products, and Corporate and Other. Included in the operating loss of Corporate and Other are non-allocable corporate expenditures and expenses related to our research and development activities in the area of cardiology, the latter of which amounted to $4.3 million, net of the ITI funding of $1.9 million (Note 8), and $3.6 million for the three months ended March 31, 2005 and 2004, respectively. Total assets in the area of cardiology, which are included in Corporate and Other in the tables below, amounted to $57.3 million at March 31, 2005 and $8.6 million at December 31, 2004.

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

(in thousands)	Consumer Diagnostic Products	Vitamins and Nutritional Supplements	Professional Diagnostic Products	Corporate and Other	Total
Three Months Ended March 31, 2005					
Net revenue to external customers	$ 43,420	$ 16,921	$ 31,271	$	$ 91,612
Operating income (loss)	6,941	(1,860)	(2,772)	(8,790)	(6,481)
Assets	246,534	51,241	310,885	62,947	671,607
At December 31, 2004					
Assets	243,001	48,072	263,169	12,936	567,178
Three Months Ended March 31, 2004					
Net revenue to external customers	40,418	20,291	29,992		90,701
Operating income (loss)	3,578	(30)	3,363	(3,096)	3,815

(11) Material Contingencies and Legal Settlements

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

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

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

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

(12) Recent accounting pronouncements

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

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment,* or SFAS No. 123R. SFAS No. 123R addresses the accounting for transactions in which a company receives employee services in exchange for (a) equity instruments of the company or (b) liabilities that are based on the fair value of the company s equity instruments or that may be settled by the issuance of such equity instruments. It eliminates the ability to account for share-based compensation transactions using APB Opinion No. 25 and generally requires that such transactions be accounted for using a fair-value-based method. As permitted by the current SFAS No. 123, we have been accounting for share-based compensation to employees using APB Opinion No. 25 s intrinsic value method and, as such, we generally recognize no compensation cost for employee stock options. Under the original guidance of SFAS No. 123R, we were to adopt the statement s provisions for the interim period beginning after June 15, 2005. However, in April 2005, as a result of an action by the Securities and Exchange Commission, companies are allowed to adopt the provisions of SFAS No. 123R at the beginning of their fiscal year that begins after June 15, 2005. Consequently, we will adopt SFAS No. 123R on January 1, 2006. We expect that the requirement to expense stock options and other equity interests that have been or will be granted pursuant to our equity incentive program will significantly increase our operating expenses and result in lower earnings per share. See note 4 of these consolidated financial statements for the effect of accounting for stock-based compensation using the fair-value-based method. The adoption of SFAS No. 123R will have no impact on our cash flows.

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

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(13) Guarantor Financial Information

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

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

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

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF OPERATIONS

For the Three Months Ended March 31, 2005

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	$ 5,478	$ 50,778	$ 45,339	$ (12,204)	$ 89,391
License revenue		31	2,190		2,221
Net revenue	5,478	50,809	47,529	(12,204)	91,612
Cost of sales	5,617	43,033	24,564	(13,498)	59,716
Gross profit	(139)	7,776	22,965	1,294	31,896
Operating expenses:					
Research and development	141	1,115	5,976		7,232
Sales and marketing	480	7,177	9,373		17,030
General and administrative	3,308	3,622	7,185		14,115
Total operating expenses	3,929	11,914	22,534		38,377
Operating (loss) income	(4,068)	(4,138)	431	1,294	(6,481)
Equity in earnings of subsidiaries, net of tax	3,614			(3,614)	
	(4,245)	(484)	(1,343)	1,060	(5,012)

Interest expense, including amortization of discounts and write off of deferred financing costs					
Other (expense) income, net	(3,074)	8,660	324	(999)	4,911
(Loss) income before income taxes	(7,773)	4,038	(588)	(2,259)	(6,582)
Income tax provision	322	718	473		1,513
Net (loss) income	$ (8,095)	$ 3,320	$ (1,061)	$ (2,259)	$ (8,095)

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF OPERATIONS

For the Three Months Ended March 31, 2004

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	$ 4,775	$ 50,074	$ 44,198	$ (10,846)	$ 88,201
License revenue		22	2,478		2,500
Net revenue	4,775	50,096	46,676	(12,327)	90,701
Cost of sales	5,044	38,295	21,776	(11,323)	53,792
Gross profit	(269)	11,801	24,900	477	36,909
Operating expenses:					
Research and development	96	628	6,699		7,423
Sales and marketing	471	6,597	7,283		14,351
General and administrative	2,315	3,544	5,461		11,320
Total operating expenses	2,882	10,769	19,443		33,094
Operating (loss) income	(3,151)	1,032	5,457	477	3,815
Equity in earnings of subsidiaries, net of tax	964			(964)	
Interest expense, including amortization of discounts and write off of deferred financing costs	(3,173)	(3,934)	(1,304)	641	(7,770)
Other income (expense), net	731	150	207	(641)	447
(Loss) income before income taxes	(4,629)	(2,752)	4,360	(487)	(3,508)
Income tax (benefit) provision	(958)	185	936		163
Net (loss) income	$ (3,671)	$ (2,937)	$ 3,424	$ (487)	$ (3,671)

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING BALANCE SHEET

March 31, 2005

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
ASSETS					
Current Assets:					
Cash and cash equivalents	$ 284	$ 11,213	$ 22,170	$	$ 33,667
Accounts receivable, net of allowances	1,934	36,548	19,332		57,814
Inventories	5,830	43,221	21,104	(4,718)	65,437
Deferred tax assets		142	2,819		2,961
Prepaid expenses and other current assets	2,135	3,585	8,408		14,128
Intercompany receivables	55,613	18,545	15,886	(90,044)	
Total current assets	65,796	113,254	89,719	(94,762)	174,007
Property, plant and equipment, net	2,858	30,173	36,213		69,244
Goodwill	55,250	109,116	94,520		258,886
Other intangible assets with indefinite lives	5,000	12,420	37,936		55,356
Core technology and patents, net	31,454	5,871	31,215		68,540
Other intangible assets, net	5,000	19,950	10,495		35,445
Deferred financing costs, net, and other non-current assets	6,524	1,751	1,060		9,335
Deferred tax assets			748	46	794
Investment in subsidiaries	276,676	(1,020)		(275,656)	
Intercompany notes receivable	95,425	15,089	2	(110,516)	
Total assets	$ 543,983	$ 306,604	$ 301,908	$ (480,888)	$ 671,607
LIABILITIES AND STOCKHOLDERS EQUITY					
Current liabilities:					
Current portion of long-term debt	$	$	$ 329	$	$ 329
Current portion of capital lease obligations		486	6		492
Accounts payable	2,775	22,978	13,718		39,471
Accrued expenses and other current liabilities	14,050	17,028	31,210		62,288
Intercompany payables	17,835	21,595	50,614	(90,044)	
Total current liabilities	34,660	62,087	95,877	(90,044)	102,580
Long-term liabilities:					
Long-term debt, net of current portion	169,306	20,000	22,009		211,315
Capital lease obligations, net of current portion		1,310	2		1,312
Deferred tax liabilities	17,064	4,401	7,261		28,726
Other long-term liabilities		29	4,692		4,721
Intercompany notes payable		53,221	57,295	(110,516)	

Total long-term liabilities	186,370	78,961	91,259	(110,516)	246,074
Stockholders equity	322,953	165,556	114,772	(280,328)	322,953
Total liabilities and stockholders equity	$ 543,983	$ 306,604	$ 301,908	$ (480,888)	$ 671,607

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING BALANCE SHEET

December 31, 2004

	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	40,061	19,815	(6,073)	60,143
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	91,934	78,675	(84,591)	150,666
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	264,539	(966)		(263,573)	
Intercompany notes receivable	114,439	15,089		(129,528)	
Total assets	$ 473,091	$ 283,151	$ 288,582	$ (477,646)	$ 567,178
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	17,298	22,180		51,886
Intercompany payables	13,640	15,964	48,914	(78,518)	
Total current liabilities	27,802	53,220	82,282	(78,518)	84,786
Long-term liabilities:					
Long-term debt, net of current portion	169,256	20,000	12		189,268
Capital lease obligations, net of current portion		1,397	4		1,401
Deferred tax liabilities	1,352	3,821	7,423		12,596
Other long-term liabilities		29	4,417		4,446
Intercompany notes payable		53,221	76,307	(129,528)	
Total long-term liabilities	170,608	78,468	88,163	(129,528)	207,711
Stockholders equity	274,681	151,463	118,137	(269,600)	274,681

Total liabilities and stockholders equity	$ 473,091	$ 283,151	$ 288,582	$ (477,646)	$ 567,178

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF CASH FLOWS

For the Three Months Ended March 31, 2005

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Operating Activities:					
Net (loss) income	$ (8,095)	$ 3,320	$ (1,061)	$ (2,259)	$ (8,095)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:					
Equity in earnings of subsidiaries, net of tax	(3,614)			3,614	
Interest expense related to amortization and/or write-off of noncash original issue discount and deferred financing costs	292	96	55		443
Depreciation and amortization	304	2,285	3,613		6,202
Deferred income taxes	112	526			638
Other noncash items	(25)	(6)	(37)		(68)
Minority interest in subsidiary			207		207
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net	726	5,079	2,883		8,688
Inventories	510	(572)	(1,595)	(1,355)	(3,012)
Prepaid expenses and other current assets	(857)	(640)	(2,979)		(4,476)
Intercompany payables or receivables	5,790	(2,900)	(3,304)	414	
Accounts payable	1,098	1,329	2,921		5,348
Accrued expenses and other current liabilities	289	(951)	10,018		9,356
Other non-current liabilities			76		76
Net cash (used in) provided by operating activities	(3,470)	7,566	10,797	414	15,307

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF CASH FLOWS (CONTINUED)

For the Three Months Ended March 31, 2005

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

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF CASH FLOWS

For the Three Months Ended March 31, 2004

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Operating Activities:					
Net (loss) income	$ (3,671)	$ (2,937)	$ 3,424	$ (487)	$ (3,671)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:					
Equity in earnings of subsidiaries, net of tax	(964)			964	
Interest expense related to amortization and/or write-off of noncash original issue discount and deferred financing costs	268	2,747	296		3,311
Noncash charge related to interest rate swap agreement	64				64
Depreciation and amortization	618	1,838	3,119		5,575
Deferred income taxes	(963)	262			(701)
Other noncash items			(19)		(19)
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net	1,167	1,560	(2,704)		23
Inventories	(1,023)	(462)	(1,479)	(477)	(3,441)
Prepaid expenses and other current assets	(185)	(187)	968		596
Intercompany payables or receivables	(498)	2,636	(2,403)	265	
Accounts payable	(2,696)	(1,668)	(1,456)		(5,820)
Accrued expenses and other current liabilities	1,457	(1,785)	2,698		2,370
Net cash (used in) provided by operating activities	(6,426)	2,004	2,444	265	(1,713)

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATING STATEMENT OF CASH FLOWS (CONTINUED)

For the Three Months Ended March 31, 2004

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

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

Forward-Looking Statements

As noted above, this quarterly report on Form 10-Q, including this Item 2, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements in this Item 2 include, without limitation, statements regarding our expectations with respect to benefits to be realized as a result of synergies relating to our acquisitions, net product sales, our funding plans for our future working capital needs and commitments, and the impact of our acquisitions. Actual results or developments could differ materially from those projected in such statements as a result of numerous factors, including, without limitation, those risks and uncertainties set forth below under Certain Factors Affecting Future Results and Special Statement Regarding Forward-Looking Statements. The following discussion and analysis of our financial condition and results of operations should be read in light of those risks and uncertainties and in conjunction with our accompanying consolidated financial statements and notes thereto.

Financial Overview

For the three months ended March 31, 2005, we recorded net revenue of $91.6 million, compared to $90.7 million for the three months ended March 31, 2004. Adjusted for the favorable impact of currency translation, net revenue for the first quarter of 2005 was essentially consistent with that for the first quarter of 2004. Our combined consumer and professional diagnostics businesses enjoyed a 5% growth, adjusted for the impact of currency translation, while this growth was offset by the decline in our vitamins and nutritional supplements business.

For the three months ended March 31, 2005, we incurred a net loss of $8.1 million, compared to a net loss of $3.7 million for the three months ended March 31, 2004. The significant loss for the first quarter of 2005, compared to the first quarter of 2004, resulted from: (i) a $1.6 million negative impact on gross profit due to a recall of two of our drugs of abuse diagnostic products following our decision to withdraw the products 510(k)s, (ii) margin deterioration in our vitamins and nutritional supplements business which affected our gross profit by $1.5 million, (iii) increased sales and marketing spending of $1.9 million, (iv) increased legal spending of $2.1 million due to our continued aggressive defense and enforcement of our intellectual property, (v) an increase of $1.2 million in operating expenses due to acquisitions, and (vi) a $4.3 million legal settlement with Princeton BioMeditech Corporation, or PBM. The negative impacts on the first quarter of 2005 financial results were offset by an $8.4 million gain from a legal settlement of class action suits against several raw material suppliers in our vitamins and nutritional supplements business. In addition, we recently announced a settlement with Quidel Corporation, or Quidel, in which Quidel agreed to pay us net, $17 million for a license to our intellectual property for past product sales and an ongoing net royalty of 8.5% on future sales of their lateral flow products. The payment of $17 million from Quidel will be included in our results for the second quarter of 2005.

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

Our Acquisition of the Rapid Diagnostics Business from Abbott Laboratories

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

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

With respect to marketing synergies, we have enjoyed the savings that we anticipated at the time of the acquisition with respect to the addition of the Fact plus product line to our existing consumer diagnostics business, which has sold and distributed Fact plus with nominal increases in consumer sales and marketing infrastructure. These marketing synergies benefited sales and marketing expense as a percentage of net product sales by 24 basis points for the three months ended March 31, 2005.

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

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

Results of Operations

Net Product Sales, Total and by Business Segment. Total net product sales increased by $1.2 million, or 1%, to $89.4 million for the three months ended March 31, 2005 from $88.2 million for the three months ended March 31, 2004. Excluding the favorable impact of currency translation, net product sales for the three months ended March 31, 2005 increased by $0.2 million, compared to the three months ended March 31, 2004. Net product sales by business segment for the three months ended March 31, 2005 and 2004 are as follows:

(in thousands)	Three Months ended March 31, 2005	2004	% Change
Consumer diagnostic products	$ 41,935	$ 38,750	8%

Vitamins and nutritional supplements		16,921		20,290	(17)%
Professional diagnostic products		30,535		29,161	5%
Total net product sales	$	89,391	$	88,201	