INVERNESS MEDICAL INNOVATIONS INC
Form 10-Q/A
August 28, 2002

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q/A
(Amendment No. 1)

(Mark One)

ý **Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the quarterly period ended March 31, 2002**

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

The number of shares outstanding of the registrant's common stock as of May 8, 2002 was 9,410,960.

INVERNESS MEDICAL INNOVATIONS, INC.

Explanatory Note

This Amendment No. 1 to Inverness Medical Innovations, Inc.'s Quarterly Report on Form 10-Q for the three months ended March 31, 2002 is being filed in order to restate reported financial results for the three months ended March 31, 2002 to reflect an adjustment to purchase accounting in connection with our acquisition of certain entities and businesses of Unilever plc (the "Unipath businesses"), to reclassify certain sales incentives expenses from sales and marketing expenses to net product sales for all periods presented upon the adoption of Emerging Issues Task Force Issue No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer or a Reseller of the Vendor's Products*, and to make certain additions to Note 5 of the Notes to Consolidated Financial Statements, including Note 5(b).

FORM 10-Q

For the Quarterly Period Ended March 31, 2002

This quarterly report on Form 10-Q contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Readers can identify these statements by forward-looking words such as "may", "could", "should", "would", "intend", "will", "expect", "anticipate", "believe", "estimate", "continue" or similar words. There are a number of important factors that could cause actual results of Inverness Medical Innovations, Inc. and its subsidiaries to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, challenges in operating as a stand-alone company as a result of our split-off from Inverness Medical Technology, Inc., our former parent company, which was merged with a subsidiary of Johnson & Johnson on November 21, 2001, difficulties in integrating acquired businesses and operating them profitably, difficulties in obtaining financing on satisfactory terms, manufacturing and shipping problems or delays, the risks of product defects and failure to meet strict regulatory requirements both in the United States and abroad, intense competition and economic trends which could reduce our market share, limit our ability to increase market share or decrease our operating margins as a result of competitive pricing pressures, as well as other 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 30 and 46, respectively, in this quarterly report on Form 10-Q and should not place undue reliance on our forward-looking statements. These forward-looking statements were based on information, plans and estimates at the date of this report. We undertake no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes.

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

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PART I FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(UNAUDITED)

	Three Months Ended March 31,	
	2002	**2001**
Net product sales	$ 36,540,687	$ 11,484,788
License and other revenue	706,099	
Net revenue	37,246,786	11,484,788
Cost of sales	18,240,283	5,980,191
Gross profit	19,006,503	5,504,597
Operating expenses:		
Charge related to asset impairment (Note 6)	12,681,581	
Research and development	3,366,426	298,791
Sales and marketing	9,614,966	1,807,403
General and administrative	6,889,326	1,883,628
Stock-based compensation (Note 7)*	10,144,937	
Total operating expenses	42,697,236	3,989,822
Operating (loss) income	(23,690,733)	1,514,775
Interest expense, including amortization of original issue discount and beneficial conversion feature	(4,147,960)	(372,524)
Other income (expense), net	530,620	(78,744)
(Loss) income from continuing operations before income taxes	(27,308,073)	1,063,507
Provision for income taxes	506,392	353,769
(Loss) income from continuing operations	(27,814,465)	709,738
Loss from discontinued operations, net of taxes of $226,000		(581,203)
(Loss) income before extraordinary item and accounting change	(27,814,465)	128,535
Extraordinary gain (Note 8)	8,505,989	
Cumulative effect of a change in accounting principle (Note 6)	(12,148,205)	
Net (loss) income	$ (31,456,681)	$ 128,535

	Three Months Ended March 31,	
(Loss) income per common share basic and diluted (Note 10):		
(Loss) income from continuing operations	$ (4.14)	$ 0.12
Net (loss) income	$ (4.66)	$ 0.02
Weighted average shares	7,082,000	6,062,000

*

The charge for stock-based compensation for the three months ended March 31, 2002 was classified as general and administrative expenses.

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

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(UNAUDITED)

	March 31, 2002	December 31, 2001
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,405,195	$ 52,023,531
Accounts receivable, net of allowances of $2,686,000 at March 31, 2002 and $2,595,000 at December 31, 2001	27,103,906	21,576,203
Inventory	27,279,085	14,781,990
Deferred income taxes	1,466,786	1,466,786
Prepaid expenses and other current assets	5,089,477	4,973,659
Total current assets	83,344,449	94,822,169
Property, plant and equipment, net	42,575,533	20,526,228
Goodwill, net	72,372,621	85,375,217
Trademarks and other intangible assets, net	61,899,007	75,390,396
Deferred financing costs and other assets, net	3,325,568	2,407,134
Total assets	$ 263,517,178	$ 278,521,144
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 6,887,247	$ 20,819,383
Accounts payable	21,876,383	10,264,023
Accrued expenses and other current liabilities	38,188,820	42,716,768

	March 31, 2002	December 31, 2001
Total current liabilities	66,952,450	73,800,174
Long-term liabilities:		
Long-term debt	58,796,813	57,304,834
Deferred income taxes	2,005,309	2,044,019
Other liabilities	3,799,850	3,863,550
Total long-term liabilities	64,601,972	63,212,403
Commitments and contingencies		
Series A redeemable convertible preferred stock, $0.001 par value:		
Authorized 2,666,667 shares Issued 2,526,913 shares at March 31, 2002 and 1,995,000 shares at December 31, 2001		
Outstanding 2,360,246 shares at March 31, 2002 and 1,995,000 shares at December 31, 2001	61,514,135	51,894,435
Stockholders' equity:		
Preferred stock, $0.001 par value:		
Authorized 2,333,333 shares, none issued		
Common stock, $0.001 par value:		
Authorized 50,000,000 shares		
Issued and outstanding 9,126,588 at March 31, 2002 and 8,681,744 shares at December 31, 2001	9,127	8,682
Additional paid-in capital	151,662,720	147,410,812
Notes receivable from stockholders	(14,691,097)	(14,691,097)
Deferred compensation		(10,144,937)
Accumulated deficit	(67,622,520)	(34,636,572)
Accumulated other comprehensive income	1,090,391	1,667,244
Total stockholders' equity	70,448,621	89,614,132
Total liabilities and stockholders' equity	$ 263,517,178	$ 278,521,144

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

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(UNAUDITED)

	Three Months Ended March 31,	
	2002	**2001**
Cash Flows from Operating Activities:		

	Three Months Ended March 31,	
Net (loss) income	$ (31,456,681)	$ 128,535
Loss from discontinued operations		581,203
Net (loss) income, excluding discontinued operations	(31,456,681)	709,738
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:		
Noncash interest expense related to amortization of original issue discount and beneficial conversion feature	2,722,604	
Capitalized interest expense	108,940	
Noncash stock-based compensation expense	10,144,937	
Noncash extraordinary item	(8,750,663)	
Noncash charge related to asset impairment and cumulative effect of a change in accounting principle	24,829,786	
Depreciation and amortization	1,940,089	798,177
Capital contribution from Inverness Medical Technology, Inc. related to income taxes for Inverness Medical, Inc.		75,000
Changes in assets and liabilities, net of acquisition:		
Accounts receivable, net	46,618	186,780
Inventory	(1,440,473)	(457,518)
Prepaid expenses and other current assets	818,631	(289,193)
Accounts payable	4,335,531	(912,732)
Accrued expenses and other current liabilities	(7,989,101)	(30,056)
Due to Inverness Medical Technology, Inc. and affiliates		680,705
Net cash (used in) provided by continuing operations	(4,689,782)	760,901
Net cash provided by discontinued operations		639,683
Cash Flows from Investing Activities:		
Purchases of property, plant and equipment	(384,222)	(300,128)
Cash paid for purchase of IVC Industries, Inc., net of cash acquired	(8,120,306)	
Cash paid for purchase of Unipath businesses	(3,354,551)	
Decrease in other assets	131,126	
Net cash used in investing activities	(11,727,953)	(300,128)
Cash Flows from Financing Activities:		
Cash paid for deferred financing costs	(498,271)	(47,524)
Proceeds from issuance of common and preferred stock	20,863,068	
Repayments of notes payable	(33,347,372)	(1,760,416)
Contribution from Inverness Medical Technology, Inc.		500,045
Net cash used in financing activities	(12,982,575)	(1,307,895)
Foreign exchange effect on cash and cash equivalents	(218,026)	550,312
Net (decrease) increase in cash and cash equivalents	(29,618,336)	342,873
Cash and cash equivalents, beginning of period	52,023,531	3,071,477
Cash and cash equivalents, end of period	$ 22,405,195	$ 3,414,350
Supplemental Disclosure of Cash Flow Information:		
Interest paid	$ 1,023,515	$ 232,399

	Three Months Ended March 31,	
Taxes paid	$ 346,010	$ 5,000
Supplemental Disclosure of Noncash Activities:		
On March 19, 2002, the Company acquired IVC Industries, Inc. (Note 5) -		
Accounts receivable	$ 5,205,319	$
Inventory	9,831,608	
Property, plant and equipment	23,016,267	
Other assets	1,754,639	
Accounts payable and accrued expenses	(13,029,818)	
Cash paid for purchase of IVC Industries, Inc., net of cash acquired	(8,120,306)	
	18,657,709	
Fair value of assumed and issued fully-vested stock options	(1,298,674)	
Assumed liabilities	$ 17,359,035	$

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 (the "Company" or "Innovations") 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 of the Company in conformity with accounting principles generally accepted in the United States. The Company filed audited consolidated financial statements for the year ended December 31, 2001, which included information and footnotes necessary for such presentation and were included in its Annual Report on Form 10-K, as amended, filed with the Securities and Exchange Commission on April 2, 2002. These unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto for the year ended December 31, 2001.

On November 21, 2001, pursuant to an Agreement and Plan of Split-Off and Merger dated May 23, 2001 (the "Merger Agreement"), Johnson & Johnson acquired Inverness Medical Technology, Inc. ("IMT") in a merger transaction and, simultaneously, Innovations, then a subsidiary of IMT, was split-off from IMT as a separate publicly traded company. Pursuant to the terms of the Merger Agreement and related agreements, immediately prior to the consummation of the transaction, IMT restructured its operations so that all of IMT's non-diabetes businesses (women's health, nutritional supplements and clinical diagnostics) were held by Innovations and Innovations' subsidiaries. At the closing of the transaction, all of the shares of Innovations common stock held by IMT were split-off from IMT in a pro rata distribution to IMT stockholders and IMT (which then consisted primarily of its diabetes care business) merged with and became a wholly-owned subsidiary of Johnson & Johnson.

Innovations was incorporated on May 11, 2001 for the purpose of receiving IMT's contribution of its women's health, nutritional supplements and clinical diagnostics businesses in connection with the transactions described in the Merger Agreement and related agreements. Innovations' historical consolidated financial statements include IMT subsidiaries and businesses that were contributed to Innovations as if such

subsidiaries and businesses were historically organized in a manner consistent with the restructuring set forth in the Merger Agreement and related agreements. The primary subsidiaries and businesses that were contributed to Innovations by IMT are as follows:

Inverness Medical, Inc. ("IMI"), a U.S. corporation, and its wholly-owned subsidiary, Can-Am Care Corporation ("Can-Am"), a U.S. corporation

Cambridge Diagnostics Ireland Ltd. ("CDIL"), an Irish corporation

Orgenics, Ltd. ("Orgenics"), an Israeli corporation

The women's health business of Inverness Medical Europe GmbH ("IME"), a German corporation

Inverness Medical Benelux Bvba ("IMB"), a Belgian corporation

The women's health assets held by IMT, plus allocations to Innovations of IMT common expenditures

Innovations has consolidated the financial statements of the above individual legal entities and the newly acquired entities and businesses, as discussed below, along with the assets, liabilities, revenues and expenses of the businesses. For the period prior to the split-off and merger, the financial statements were combined in a manner consistent with the consolidated financial statements. All material intercompany transactions and balances have been eliminated.

Pursuant to the Merger Agreement and related agreements, on November 21, 2001, immediately prior to the split-off and merger, Innovations transferred to IMT those entities or businesses that conduct business in the diabetes segment, principally the Can-Am subsidiary of IMI and the diabetes businesses of CDIL and IMB. As a result, Innovations has presented the historical diabetes operations of its subsidiaries as discontinued operations in the accompanying consolidated statements of operations and cash flows for the three months ended March 31, 2001 under Accounting Principles Board ("APB") Opinion No. 30, *Reporting the Results of Operations Reporting the Effects of Disposal of a Segment of a Business, and Extraordinary, Unusual and Infrequently Occurring Events and Transactions*.

At the closing of the transactions set forth in the Merger Agreement and related agreements, IMT distributed to its stockholders one Innovations share for every five IMT shares held. In order for IMT to do so, Innovations declared a stock split, effected as a dividend. Accordingly, earnings per share information for the three months ended March 31, 2001 represents the actual number of shares of Innovations common stock outstanding as of the date of its incorporation, effected for the fixed exchange ratio set forth in the Merger Agreement and related agreements and the related stock split (Note 10).

Innovations' consolidated statements of operations and cash flows for the three months ended March 31, 2001 also reflect the allocation of IMT's common expenditures. Such allocations have been made in accordance with Staff Accounting Bulletin ("SAB") No. 55, *Allocation of Expenses and Related Disclosure in Financial Statements of Subsidiaries, Divisions or Lesser Business Components of Another Entity*.

The accompanying consolidated statements of operations and cash flows for the three months ended March 31, 2001 reflect substantially all costs of doing business, including those incurred by IMT on Innovations' behalf. Costs that are clearly identifiable as being applicable to an Innovations subsidiary or business have been allocated to Innovations. The most significant costs included in this category include salary and benefits of certain employees and legal and other professional fees. Costs of centralized departments and corporate operations that serve all operations have been allocated, where such allocations would be material, using relevant allocation measures, such as estimated percentage of time worked for salary and benefits of certain executives and employees and square feet occupied for occupancy costs in shared facilities. Corporate costs that clearly relate to businesses or subsidiaries that were retained by IMT or that do not provide any significant direct or indirect benefit to Innovations have not been allocated to Innovations. For the period prior to the split-off and merger, Innovations accounted for income taxes using the separate return method, pursuant to Statement of Financial Accounting Standard ("SFAS") No. 109, *Accounting for Income Taxes*. IMT has historically charged interest on loans made to its subsidiaries. Accordingly, Innovations' consolidated statement of operations for the three months ended March 31, 2001 reflect interest expense on amounts due to entities not included in Innovations' consolidated financial statements (primarily to IMT). Interest expense for the three months ended March 31, 2001 also reflects amounts recorded on third-party

notes payable when such notes relate specifically to Innovations' operations. Interest expense for the three months ended March 31, 2001 does not include amounts recorded on general corporate borrowings of IMT. Innovations believes that the allocation methods described herein are reasonable and fairly reflect its financial position and results of operations for the period prior to the split-off and merger.

Since the split-off and merger, as described above, on December 20, 2001, the Company acquired certain entities and businesses of Unilever Plc (the "Unipath businesses") and on March 19, 2002, the Company acquired IVC Industries, Inc. ("IVC"). The Unipath businesses manufacture and distribute women's health and clinical diagnostics products and IVC manufactures and distributes vitamins and nutritional supplements. The results of the Unipath businesses and IVC are included in the consolidated financial statements of the Company since their respective acquisition dates. The Unipath businesses are comprised of the following entities and businesses:

Unipath Ltd. ("Unipath UK"), a British corporation, and its wholly-owned subsidiary, Unipath Management Ltd. ("UML"), also a British corporation

The women's health business of Unipath conducted in the United States ("Unipath US")

Unipath Diagnostics GmbH ("Unipath Germany"), a German corporation

Unipath Scandinavia AB ("Unipath Scandinavia"), a Swedish corporation

Unipath B.V. ("Unipath Netherlands"), a Dutch corporation

Unipath assets, primarily intellectual property, held by Unilever Plc, along with the related license revenue

(2) Cash and Cash Equivalents

The Company considers all highly liquid cash investments with maturities of three months or less at the date of acquisition to be cash equivalents. At March 31, 2002, the Company's 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:

	March 31, 2002	December 31, 2001
Raw materials	$ 11,107,747	$ 6,895,192
Work-in-process	5,985,152	1,378,503
Finished goods	10,186,186	6,508,295
	$ 27,279,085	$ 14,781,990

(4) Nonrecurring and Noncash Items

For the three months ended March 31, 2002, the Company recorded the following nonrecurring or noncash items: (a) noncash interest expense of $2,723,000 representing the amortization of original issue discount and beneficial conversion feature related to the Company's

subordinated promissory notes, (b) a total noncash asset impairment charge of $24,830,000, of which $12,148,000 was recorded as a cumulative effect of a change in accounting principle in the accompanying consolidated statements of operations, representing the value of the impaired goodwill and trademarks relating to certain of the Company's existing nutritional supplement business (Note 6), (c) noncash stock-based compensation of $10,145,000 (Note 7), and (d) an extraordinary gain of $8,506,000 related to the early retirement of subordinated promissory notes and the related repurchase of the beneficial conversion feature associated with these subordinated promissory notes (Note 8).

For the three months ended March 31, 2001, the Company recorded a loss from discontinued operations of $581,000 which represented the results of operations of the diabetes related businesses of the entities that were contributed to the Company as part of the split-off from IMT on November 21, 2001. These diabetes related businesses were simultaneously transferred back to IMT on November 21, 2001 (Note 1).

(5) Business Combinations

(a) Acquisition of IVC Industries, Inc.

On March 19, 2002, the Company acquired IVC, a manufacturer and distributor of vitamins and other nutritional supplements. The Company intends to consolidate its vitamin and nutritional supplement manufacturing at IVC and discontinue most of its outsourced manufacturing arrangements. The aggregate purchase price of IVC was approximately $27,254,000, which consisted of $5,619,000 in cash representing $2.50 for each outstanding share of IVC's common stock, fully-vested stock options to purchase an aggregate of 115,744 shares of the Company's common stock with an aggregate fair value of $1,299,000, approximately $1,613,000 in estimated costs to exit certain activities of IVC, primarily severance costs of involuntarily terminated employees in accordance with Emerging Issues Task Force ("EITF") Issue No. 95-3, *Recognition of Liabilities in Connection with a Purchase Business Combination*, $17,359,000 in assumed debt and approximately $1,364,000 in estimated direct acquisition costs. Of the $1,613,000 estimated severance costs, none has been paid as of March 31, 2002. The acquisition was funded by the Company's existing cash. The aggregate purchase price for IVC was allocated to the acquired assets and assumed liabilities as follows:

Cash and cash equivalents	$ 476,000
Accounts receivable	5,205,000
Inventory	9,832,000
Property, plant and equipment	23,016,000
Other assets	1,755,000
Accounts payable and accrued expenses	(13,030,000)
	$ 27,254,000

The above allocation of the aggregate purchase price for IVC is preliminary. Factors that could impact the aggregate purchase price and its related allocation include changes in estimated costs associated with exit plans and estimated direct acquisition costs.

The acquisition of IVC was accounted for as a purchase under SFAS No. 141, *Business Combinations*. Accordingly, the results of IVC have been included in the accompanying consolidated statements of operations since the date of acquisition. The acquired assets and assumed liabilities of IVC were assigned to the Company's nutritional supplements business reporting unit which is included in its consumer diagnostic products business segment.

The following table presents selected unaudited interim financial information of the Company, including IVC and the Unipath businesses, the latter of which the Company acquired on December 20, 2001, as if the acquisitions had occurred on January 1, 2001. These unaudited pro forma results exclude a charge of $6,980,000 to operations representing the portion of the purchase price allocated to the fair value of certain in-process research and development projects related to the Unipath acquisition. The

unaudited pro forma interim results are not necessarily indicative of the results that would have occurred had the acquisitions been consummated on January 1, 2001 or future results.

	Three Months Ended March 31,	
	2002	2001
	(unaudited pro forma)	
Net revenue	$ 47,693,000	$ 51,614,000
Cost of sales	26,812,000	26,314,000
Gross profit	20,881,000	25,300,000
Operating expenses:		
Charge related to asset impairment	12,682,000	
Research and development	3,366,000	2,732,000
Sales and marketing	11,170,000	12,260,000
General and administrative	8,472,000	7,668,000
Stock-based compensation	10,145,000	
Total operating expenses	45,835,000	22,660,000
Operating (loss) income	(24,954,000)	2,640,000
Interest and other expenses, net	(3,963,000)	(2,845,000)
Loss from continuing operations before income taxes	(28,917,000)	(205,000)
Provision for income taxes	437,000	139,000
Loss from continuing operations	(29,354,000)	(344,000)
Loss from discontinued operations		(581,000)
Loss before extraordinary item and accounting change	(29,354,000)	(925,000)
Extraordinary gain	8,506,000	
Cumulative effect of a change in accounting principle	(12,148,000)	
Net loss	$ (32,996,000)	$ (925,000)
Loss per common share basic and diluted:		
Loss from continuing operations	$ (4.36)	$ (0.06)
Net loss	$ (4.88)	$ (0.15)

(b) Acquisition of the Unipath Businesses

On December 20, 2001, the Company acquired the Unipath businesses (Note 1). As a result of this business combination, the Company reorganized the operations of the Unipath businesses for purposes of improving efficiencies and achieving economies of scale on a company-wide basis. Such reorganization affected all major cost centers at Unipath UK. Additionally, most business activities of Unipath US were merged into the Company's existing U.S. businesses. As of March 31, 2002, the total number of involuntarily terminated employees was 64 of which 16 remain to be terminated. The Company accounted for such reorganization in accordance with EITF Issue No. 95-3. The total estimated amount of restructuring costs of the Unipath businesses, which consists primarily of

severance costs, was included as part of the Unipath purchase price. As of March 31, 2002, total estimated restructuring costs, including related unfunded pension liability, amounted to $5,206,000, of which $1,108,000 has been paid and $4,098,000 remained in accrued expenses and other liabilities. During the three months ended March 31, 2002, the Company accrued additional severance and related costs of $232,000 as it continued to finalize the restructuring plan. Such additions to accrued severance costs were recorded as adjustments to the Unipath purchase price. As of March 31, 2002, the Company has not yet finalized the Unipath restructuring plan although only a small number of cost centers remain to be reviewed for restructuring. Any adjustments to the estimated severance costs upon finalizing the restructuring plan will result in adjustments to the Unipath purchase price.

(6) Asset Impairment

On January 1, 2002, the Company adopted SFAS No.142, *Goodwill and Other Intangible Assets*. SFAS No. 142 addresses changes in the financial accounting and reporting for acquired goodwill and other intangible assets with indefinite lives. SFAS No. 142 also provides specific guidance for determining and measuring impairment of such intangible assets. Based upon the results of an independent impairment review, as required by SFAS No. 142, the Company recorded an impairment charge of $12,148,000, representing the remaining goodwill related to its reporting unit that comprises the nutritional supplement lines the Company acquired in 1997. This amount represented the excess of the carrying value over the fair value of such asset. The fair value was determined using a combination of the income approach and the market approach of valuing a business. The income approach valued the business by discounting projected future cash flows and the market approach valued the security underlying the business by comparing it to those of similar businesses. The most significant facts and circumstances that led to the conclusion of this impairment were (a) future cash flows from these nutritional supplement lines are expected to be reduced, (b) selling, general and administrative expenses relating to these nutritional supplement lines are forecasted to increase as a percentage of sales, and (c) this nutritional supplements business is experiencing a larger percentage decline in revenues than most of the comparable businesses of other companies. This impairment charge was recorded in accordance with SFAS No. 142 as a cumulative effect of a change in accounting principle in the accompanying statement of operations for three months ended March 31, 2002.

Because the independent appraisal of the fair value of the reporting unit underlying the Company's nutritional supplements business indicated an impairment of that reporting unit, as discussed above, the Company proceeded to also obtain an independent impairment review of the carrying value assigned to related trademarks and brand names in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. The results of the impairment review under SFAS No. 144 indicated an impairment of the carrying value of such trademarks and brand names because the full carrying amount of these intangible assets was not expected to be recoverable and exceeded its fair value. The carrying amount of these intangible assets was not recoverable because it exceeded the sum of the undiscounted cash flows expected to result from the use and eventual disposition of these assets. The fair value of these intangible assets was determined using a combination of the discounted cash flow approach and the relief from royalty approach, the latter of which valued the brand names as if they were licensed from a third party. Based on these results, the Company recorded an impairment charge of $12,682,000 for the three months ended March 31, 2002, which was included in operating expenses in the accompanying statements of operations. The remaining carrying

value of these intangible assets was $4,230,000 at March 31, 2002, which is being amortized over their remaining useful lives of 20 years.

(7) Employee Stock Award

On August 15, 2001, the Company sold to its chief executive officer ("CEO") 1,168,191 shares of restricted common stock at a price of $9.13 per share. Two-thirds of the restricted stock, or 778,794 shares, vest ratably over 36 months; the remaining one-third, or 389,397 shares, vests ratably over 48 months. Except for the par value of the common stock, which was paid in cash, the CEO purchased the restricted stock with a five-year promissory note which, for accounting purposes, was treated as a non-recourse note. The balance of the promissory note is recorded as a note receivable and is classified in stockholders' equity in the accompanying consolidated balance sheets. The note bears interest at an annual rate of 4.99%. Under the terms of the original restricted stock agreement, the Company could repurchase unvested shares at cost in certain circumstances. The Company accounted for this arrangement under Financial Accounting Standards Board ("FASB") Interpretation ("FIN") No. 44, EITF Issue No. 95-16, *Accounting for Stock Compensation Arrangements with Employer Loan Features under APB Opinion No. 25*, and EITF Issue No. 00-23, *Issues Related to Accounting for Stock Compensation under APB Opinion No. 25 and FASB Interpretation No. 44*. Accordingly, on November 20, 2001, the date on which this arrangement was approved by the stockholders, the Company measured total compensation expense to be approximately $10,595,000 based on the intrinsic value of the stock on that date. The amount of compensation expense was initially deferred and amortized ratably over the vesting periods of the restricted stock. In February 2002, the terms of the restricted stock agreement were amended, pursuant to which the Company may repurchase unvested shares at the then fair value in certain circumstances. Also, in connection with this amendment, the CEO surrendered 50,000 shares of his nonqualified stock options in the Company. Because the repurchase rights on unvested shares are now at fair value, the Company fully amortized the remaining portion of the deferred compensation expense, or $10,145,000, associated with the restricted stock at the time the repurchase rights were amended. Such amortization of deferred

compensation was recorded as stock-based compensation in the accompanying consolidated statements of operations.

(8) Subordinated Promissory Notes

On March 6, 2002, the Company prepaid its then outstanding subordinated promissory notes ("Subordinated Notes") having an aggregate principal amount of $20,000,000 and related accrued interest of $568,000 using the proceeds from the issuance of series A convertible preferred stock ("Series A Preferred Stock") (Note 9). The original maturity date of the Subordinated Notes was April 1, 2002, with an extension option, and interest accrued at 12% per annum, or 18% if and when maturity date was extended. The Subordinated Notes were convertible into shares of the Company's Series A Preferred Stock at the option of the holder. Due to this convertible nature, the Company recorded a discount on the notes in the form of a beneficial conversion feature of $3,243,000 in accordance with EITF Issue No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios*, and EITF Issue No. 00-27, *Application of EITF Issue No. 98-5 to Certain Convertible Instruments*. The value assigned to the beneficial conversion feature was being amortized to interest expense over the life of the Subordinated Notes.

The Company accounted for the prepayment of the Subordinated Notes and the reacquisition of the related beneficial conversion feature as an early extinguishment of debt and recorded an extraordinary gain of $8,506,000. In accordance with EITF Issue Nos. 98-5 and 00-27, the extraordinary gain was calculated by first allocating the reacquisition price to the beneficial conversion feature, measured based on its intrinsic value at the date of extinguishment, with the residual amount allocated to the Subordinated Notes.

(9) Series A Preferred Stock

In March 2002, the Company sold to private investors 531,913 shares of Series A Preferred Stock at $39.01 per share for gross proceeds of $20,750,000 for purposes of prepaying the Subordinated Notes (Note 8). The terms of these shares of Series A Preferred Stock are the same as those shares issued in December 2001. Each share of Series A Preferred Stock accrues dividends on a quarterly basis at $2.10 per annum, but only on those days when the closing price of the Company's common stock is less than $15. As the Company's stock price did not close below $15 following the issuance of the Series A Preferred Stock, no dividends were recorded during the three months ended March 31, 2002. Dividends accrued are payable only if declared by the board of directors. Until December 31, 2003, accrued dividends, if any, must be paid in the Company's common stock. The number of shares of common stock to be issued in payment of any accrued dividends is equal to such number as is determined by dividing the aggregate amount of the accrued dividend then payable by the greater of (i) $15 and (ii) the average market price during the 30 trading day period immediately preceding the date such dividend is declared. Thereafter, the Company has the option to pay dividends in cash or common stock. The number of shares of common stock to be issued upon any voluntary conversion of one share of Series A Preferred Stock is equal to such number as is determined by dividing $30 by the conversion price in effect at the time of conversion. The conversion price was initially $15 and is subject to adjustment. The effective purchase price for the shares of common stock underlying the Series A Preferred Stock issued in March 2002 represented a $2.70 (or 12%) discount to the fair value of the Company's common stock on the issuance date. In accordance with EITF Issue No. 98-5 and EITF Issue No. 00-27, the Company recorded a discount in the form of a beneficial conversion feature on the new Series A Preferred Stock of approximately $2,867,000, which is being amortized to accumulated deficit over the redemption period (as discussed below). The amortization of this discount reduces earnings available to common stockholders in the computation of earnings per share (Note 10). The total amount of the discount for all outstanding shares of Series A Preferred Stock amortized during the three months ended March 31, 2002 was approximately $877,000. Starting on December 20, 2003, the Company may convert the Series A Preferred Stock into common stock in the event that the average closing price of its common stock exceeds $20 for any consecutive 30 trading day period.

Because the Series A Preferred Stock may be redeemed upon a vote by the holders of at least two-thirds of the outstanding Series A Preferred Stock on or after June 30, 2011, the Company has classified the outstanding Series A Preferred Stock outside of stockholders' equity in the accompanying consolidated balance sheets. The redemption price per share of Series A Preferred Stock will be equal to $30 plus a premium calculated at 5% per annum from the date of issuance. The Company recorded a premium of $652,000 for the three months ended March 31, 2002, which reduced earnings available to common stockholders in the computation of earnings per share (Note 10).

(10) Earnings Per Share

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

	Three Months Ended March 31,	
	2002	2001
Numerator:		
(Loss) income from continuing operations	$ (27,814,465)	$ 709,738
Premium and amortization of beneficial conversion feature related to Series A Preferred Stock (Note 9)	(1,529,267)	
(Loss) income from continuing operations available to common stockholders	(29,343,732)	709,738
Loss from discontinued operations		(581,203)
(Loss) income before extraordinary item and accounting change	(29,343,732)	128,535
Extraordinary gain	8,505,989	
Cumulative effect of a change in accounting principle	(12,148,205)	
Net (loss) income available to common stockholders	$ (32,985,948)	$ 128,535
Denominator:		
Weighted average shares*	7,082,000	6,062,000
(Loss) income per share basic and diluted:		
(Loss) income from continuing operations available to common stockholders	$ (4.14)	$ 0.12
Loss from discontinued operations		(0.10)
(Loss) income before extraordinary item and accounting change	(4.14)	0.02
Extraordinary gain	1.20	
Cumulative effect of a change in accounting principle	(1.72)	
Net (loss) income available to common stockholders	$ (4.66)	$ 0.02

* The number of weighted average shares for the three months ended March 31, 2001 represents the weighted average number of Innovations common shares outstanding as of the date of its incorporation, giving effect to the fixed exchange ratio set forth in the Merger Agreement and related agreements and the related stock split (Note 1).

The Company had the following potential dilutive securities outstanding during the three months ended March 31, 2002: (a) options and warrants to purchase an aggregate of 2,866,836 shares of the Company's common stock at a weighted average exercise price of $14.625 per share, (b) Series A Preferred Stock convertible into an aggregate of 4,720,492 shares of the Company's common stock, (c) 1,644,475 shares of restricted common stock issued to certain executive officers, and (d) 15,902 shares of common stock held in escrow. These potential dilutive securities were not included in the computation of diluted loss per share because the inclusion thereof would be antidilutive. There were no dilutive securities outstanding during the three months ended March 31, 2001.

(11) Comprehensive Income

The Company's only item of comprehensive income relates to foreign currency translation adjustments. Comprehensive income for the three months ended March 31, 2002 and 2001 was approximately $577,000 less than and $420,000 more than reported net (loss) income, respectively, due to foreign currency translation adjustments.

(12) Derivative Instrument

The Company entered into an interest rate swap agreement with one of its lenders effective February 25, 2002, which applies to certain of its term loans and protects both the Company and the lender against fluctuation in the London Interbank Offered Rate ("LIBOR"). The term loans originally accrue interest at LIBOR plus a range of 1.50% to 3.50%, depending on the type of loan (senior or junior). Under the interest rate swap agreement, the LIBOR rate is set at a minimum of 3.36% and a maximum of 5.00%. The Company accounts for this derivative instrument in accordance with SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and related amendments. The effect of this derivative instrument on the Company's consolidated financial statements was not material during the three months ended March 31, 2002.

(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. The Company's chief operating decision making group is composed of the CEO and members of senior management. The Company's reportable operating segments are Consumer Products (comprised of consumer diagnostic products and vitamins and nutritional supplements), Clinical Diagnostics Products and Corporate and Other.

The Company evaluates performance based on earnings, excluding noncash and nonrecurring items, before interest expense, taxes, depreciation and amortization ("EBITDA"). Segment information for the three months ended March 31, 2002 and 2001 is as follows:

	Consumer Products	Clinical Diagnostics Products	Corporate and Other	Total
Three Months Ended March 31, 2002				
Net revenue from external customers	$ 31,913,323	$ 5,333,463	$	$ 37,246,786
EBITDA	$ 2,494,557	$ 846,211	$ (1,734,274)	$ 1,606,494
Assets	$ 230,717,601	$ 22,459,366	$ 10,340,211	$ 263,517,178
At December 31, 2001				
Assets	$ 194,322,644	$ 42,023,783	$ 42,174,717	$ 278,521,144
Three Months Ended March 31, 2001				
Net revenue from external customers	$ 8,829,788	$ 2,655,000	$	$ 11,484,788
EBITDA	$ 2,412,538	$ 118,000	$ (296,330)	$ 2,234,208

	Three Months Ended March 31,	
	2002	2001
Reconciliation of EBITDA to (Loss) Income from Continuing Operations:		
EBITDA	$ 1,606,494	$ 2,234,208
Depreciation and amortization expense	(1,940,089)	(798,177)
Interest expense	(4,147,960)	(372,524)
Income taxes	(506,392)	(353,769)
Noncash charges	(22,826,518)	
(Loss) income from continuing operations	$ (27,814,465)	$ 709,738

(14) Recently Issued Accounting Standards

In June 2001, the FASB issued SFAS No. 142, which addresses changes in the financial accounting and reporting for acquired goodwill and other intangible assets with indefinite lives. Effective January 1, 2002, all existing acquired goodwill and other intangible assets with indefinite lives are no longer amortized to expense, with early adoption required for all goodwill and other intangible assets with indefinite lives acquired subsequent to June 30, 2001. The statement also provides specific guidance for determining and measuring impairment of all goodwill and other intangible assets. The Company recorded goodwill amortization of approximately $151,000 for the three months ended March 31, 2001. At March 31, 2002, the total amount of goodwill and other intangible assets with indefinite lives affected by this statement was $98,105,000, which was all acquired subsequent to June 30, 2001. Also, upon the adoption of SFAS No. 142, the Company recorded a goodwill impairment charge of $12,148,000 during the three months ended March 31, 2002 (Note 6).

In August 2001, the FASB issued SFAS No. 144, which addresses financial accounting and reporting for the impairment or disposal of long-lived assets. This statement requires that a long-lived

asset to be abandoned, exchanged for a similar productive asset, or distributed to owners in a spin-off be considered held and used until it is disposed of. The changes in this statement require that one accounting model be used for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired, and broaden the presentation of discontinued operations to include more disposal transactions. SFAS No. 144 also provides guidance for determining and measuring impairment of long-lived and intangible assets, which do not materially differ from previous guidance. The provisions of this statement are effective for financial statements issued for fiscal years beginning after December 15, 2001 and interim periods within those fiscal years, with early adoption encouraged. The provisions of this statement generally are to be applied prospectively. During the three months ended March 31, 2002, the Company recorded an impairment charge to its carrying value of certain trademarks and brand names of $12,682,000 in accordance with SFAS No. 144 (Note 6).

In November 2001, the EITF issued EITF Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer or a Reseller of the Vendor's Products*. EITF Issue No. 01-9 establishes accounting and reporting standards for vendor consideration to any purchasers of the vendor's products at any point along the distribution chain, regardless of whether the purchaser receiving the consideration is a direct customer. The Company offers certain sales incentives that fall within the scope of EITF Issue No. 01-9, such as free goods, slotting fees and cooperative advertising, to some of its customers. The Company adopted the provisions of this consensus in 2002, the effect of which was a net reclassification of $960,000 and $327,000 from sales and marketing expenses and cost of sales to net product sales during the three months ended March 31, 2002 and 2001, respectively.

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

Overview

On November 21, 2001, pursuant to an agreement and plan of split-off and merger dated May 23, 2001, Johnson & Johnson acquired Inverness Medical Technology, Inc. ("IMT"), our former parent, in a merger transaction and, simultaneously, our company, Inverness Medical Innovations, Inc., was split off from IMT as a separate publicly traded company. Immediately prior to the consummation of these transactions, IMT restructured its operations so that we and our subsidiaries would hold all of IMT's non-diabetes businesses (women's health, nutritional supplements and clinical diagnostics). At the closing of the transactions, all of the shares of our common stock held by IMT were split-off from IMT in a pro rata distribution to IMT's stockholders and IMT (which then consisted primarily of its diabetes business) merged with and became a wholly-owned subsidiary of Johnson & Johnson.

We develop, manufacture and market consumer healthcare products, including self-test diagnostic products for the women's health market and vitamins and nutritional supplements. To a lesser extent, we develop, manufacture and market clinical diagnostic products for use by medical professionals. Our consumer self-test diagnostic products allow individuals to obtain accurate information regarding various medical conditions on a confidential, non-prescription basis, without the expense, inconvenience and delay associated with physician visits or laboratory testing. This information gives individuals greater control over their health and their lives, allowing them to make informed decisions and take action to protect their health, alone or in consultation with healthcare professionals. Our existing self-test products are targeted at the women's health market, one of the largest existing markets for self-care diagnostics, and include home pregnancy detection tests and ovulation prediction

tests. We also sell a wide variety of vitamins and nutritional supplements. Our clinical diagnostic products include test kits used by smaller laboratories, physicians' offices and other point-of-care sites for the detection of pregnancy and a wide variety of infectious diseases.

On December 20, 2001, we acquired Unipath Limited, a global leader in home pregnancy and ovulation testing and natural family planning, and its associated companies and assets (the "Unipath business") from Unilever Plc ("Unilever") and certain entities affiliated with Unilever. The Unipath acquisition provides us with leading brand name consumer diagnostic products that compliment our existing value branded and private label home pregnancy detection and ovulation prediction products. Together with the acquisition of the Unipath business, we also acquired rights to certain antibody clones and other intellectual property rights.

Recent Developments

Acquisition of IVC Industries, Inc.

On March 19, 2002, we acquired IVC Industries, Inc. ("IVC"), a manufacturer and distributor of hundreds of different vitamin and nutritional supplement products sold under brand names and through private label arrangements with retailers. With the addition of IVC, we intend to consolidate our vitamin and nutritional supplement manufacturing at IVC and discontinue most of our outsourced manufacturing arrangements. The aggregate purchase price of IVC was approximately $27.3 million, which consisted of $5.6 million in cash representing $2.50 for each outstanding share of IVC's common stock, fully-vested stock options to purchase an aggregate of 115,744 shares of our common stock with an aggregate fair value of $1.3 million, approximately $1.6 million in estimated costs to exit certain activities of IVC, primarily severance costs, $17.4 million in assumed debt and approximately $1.4 million in estimated direct acquisition costs. The acquisition was funded by our existing cash.

Results of Operations

Net Product Sales. Net product sales for the three months ended March 31, 2002 increased $25.0 million, or 218%, to $36.5 million from $11.5 million for the three months ended March 31, 2001. The significant increase resulted predominantly from the recently acquired Unipath business which had net product sales of $21.2 million for the three months ended March 31, 2002. Our nutritional supplements business experienced a growth of $2.1 million, of which $1.6 million resulted from the addition of IVC. Additionally, our subsidiary in Ireland, Cambridge Diagnostics Ireland Limited ("CDIL"), contributed $2.2 million of the increase in net product sales through its diabetes related packaging contract with a subsidiary of Johnson & Johnson. Consistent with total net product sales, net product sales of our consumer products segment, which includes our consumer diagnostic products mostly targeted toward the women's health market and our vitamins and nutritional supplements, were $31.3 million for the three months ended March 31, 2002, an increase of $22.5 million, or 255%, as compared to $8.8 million for the three months ended March 31, 2001. Net product sales of our clinical diagnostics products segment for the three months ended March 31, 2002 increased $2.7 million, or 101%, to $5.3 million from $2.7 million for the three months ended March 31, 2001. The increase in sales of our clinical diagnostic products was entirely the result of the addition of the Unipath business.

License and Other Revenue. License and other revenue represent license and royalty fees from intellectual property license agreements with third-parties. These license agreements were acquired as part of the Unipath business. For the three months ended March 31, 2002, license revenue was $706,000. There were no license and other revenue for the three months ended March 31, 2001.

Gross Profit. Total gross profit for the three months ended March 31, 2002 increased $13.5 million, or 245%, to $19.0 million from $5.5 million for the three months ended March 31, 2001. Total gross margin of net product sales was 52% for the three months ended March 31, 2002 compared to 48% for the three months ended March 31, 2001. The increase in gross profit and margin of total net product sales primarily resulted from the addition of the Unipath business which generated total gross profit of $12.7 million and gross margin of 60% for the three months ended March 31, 2002. Only $291,000 of the increase in total gross profit resulted from the addition of IVC since March 19, 2002 with a corresponding gross margin of 18%. As a result of IVC's lower gross margins, we expect overall gross margins to be lower in future quarters. Gross profit from our consumer product sales was $16.3 million for the three months ended March 31, 2002, an increase of $12.2 million, or 300%, from $4.1 million for the three months ended March 31, 2001. Gross margin from our consumer product sales was 52% for the three months ended March 31, 2002 as compared to 46% for the three months ended March 31, 2001. Gross profit from our clinical diagnostics product sales was $2.7 million for the three months ended March 31, 2002, an increase of $1.3 million, or 88%, from $1.4 million for the three months ended March 31, 2001. Gross margin from our clinical diagnostic product sales was 52% for the three months ended March 31, 2002 as compared to 54% for the three months ended March 31, 2001.

Charge Related to Asset Impairment. During the three months ended March 31, 2002, we recorded a noncash impairment charge of $12.7 million to write-off a portion of the value that was assigned to trademarks and brand names related to certain of our nutritional supplement

lines we bought in 1997. This charge was recorded in connection with the results of a separate impairment review performed on the carrying value of the goodwill related to such nutritional supplement lines, as discussed below in the caption "Cumulative Effect of a Change in Accounting Principle". See Note 6 of the accompanying "Notes to Consolidated Financial Statements". No impairment charge was recorded during the three months ended March 31, 2001.

Research and Development Expense. Research and development expense for the three months ended March 31, 2002 increased $3.1 million, or 1027%, to $3.4 million from $299,000 for the three months ended March 31, 2001. The significant increase resulted from the addition of the Unipath

business, which houses a large research and development center in its facility in Bedford, England. Prior to the acquisition of the Unipath business, our research and development expense was primarily related to clinical diagnostic products incurred by our subsidiary, Orgenics Ltd. ("Orgenics"), in Israel. We anticipate a continuing increase in research and development activities and expenses in the future as a result of the Unipath business.

Sales and Marketing Expense. Sales and marketing expense for the three months ended March 31, 2002 increased $7.8 million, or 432%, to $9.6 million from $1.8 million for the three months ended March 31, 2001. Of this increase, $7.2 million resulted from the addition of the Unipath business and $184,000 resulted from the addition of IVC since its acquisition date. The remaining increase in sales and marketing expenses resulted primarily from our new radio advertising efforts in an attempt to boost our nutritional supplement product sales. Sales and marketing expense as a percentage of net product sales increased to 26% for the three months ended March 31, 2002 from 16% for the three months ended March 31, 2001.

General and Administrative Expense. General and administrative expense for the three months ended March 31, 2002 increased $5.0 million, or 266%, to $6.9 million from $1.9 million for the three months ended March 31, 2001. The addition of the Unipath business contributed $3.5 million to this increase in general and administrative expenses. During the three months ended March 31, 2002, we also incurred approximately $1.0 million in legal fees for our defenses in certain litigations which were inactive during the three months ended March 31, 2001. The remaining increase in general and administrative expense resulted primarily from increases in other professional fees, insurance and rent due to the relocation of our corporate headquarters in May 2001. General and administrative expense as a percentage of net product sales increased to 18% for the three months ended March 31, 2002 from 16% for the three months ended March 31, 2001.

Stock-Based Compensation. During the three months ended March 31, 2002, we recorded noncash compensation expenses of $10.1 million. This amount represents the amortization of the remaining deferred compensation recorded in 2001 in connection with the sale of restricted stock to our chief executive officer. We recorded this deferred compensation because the stock was sold below market value of our stock on the measurement date. The deferred compensation was originally set to amortize over the vesting period of the restricted stock. However, because of an amendment in the terms of the restricted stock agreement in February 2002, we fully amortized the deferred compensation during the three months ended March 31, 2002. See Note 7 of the accompanying "Notes to Consolidated Financial Statements". There was no charge for stock-based compensation during the three months ended March 31, 2001.

Interest Expense. Interest expense for the three months ended March 31, 2002 increased $3.8 million, or 1013%, to $4.1 million from $373,000 for the three months ended March 31, 2001. The significant increase in interest expense resulted from various debt financings obtained to fund the acquisition of the Unipath business in December 2001. Also, of the total increase in interest expense, $2.7 million was noncash and represented the amortization of original issue discount and beneficial conversion features related to such debt financings.

Other Income (Expense), Net. Other income (expense), net, includes interest income and other income and expenses. Interest income for the three months ended March 31, 2002 increased by $334,000, or 785%, to $376,000 from $43,000 for the three months ended March 31, 2001. The increase in interest income resulted from higher average cash balances during the three months ended March 31, 2002 due to a $41.4 million capitalization by IMT during our split-off from IMT in November 2001. A significant portion of other income and expense generally represents foreign currency exchange gains and losses. For the three months ended March 31, 2002, we recognized $188,000 in realized and unrealized foreign exchange transaction gains as compared to losses of $122,000 for the three months ended March 31, 2001.

Income Taxes. For the three months ended March 31, 2002, we recorded provisions of $506,000 for income taxes compared to $354,000 for the three months ended March 31, 2001. Of the provision recorded for the three months ended March 31, 2002, $471,000 related to the

Unipath business. The remaining business recorded a total provision of $35,000 for the three months ended March 31, 2002 as compared to $354,000 for the three months ended March 31, 2001. This decrease resulted from corporate losses available to offset profits in the US businesses.

(Loss) Income from Continuing Operations. Loss from continuing operations was $27.8 million, or $4.14 per basic and diluted common share, for the three months ended March 31, 2002 compared to income from continuing operations of $710,000, or $0.12 per basic and diluted common share, for the three months ended March 31, 2001. The significant loss for the three months ended March 31, 2002 resulted from various factors as described above.

Loss from Discontinued Operations. During the three months ended March 31, 2001, we recorded a loss from discontinued operations of $581,000. The discontinued operations represent the diabetes related segments of the entities that we acquired through the split-off from IMT that were then transferred back to IMT on November 21, 2001. See Note 1 of the accompanying "Notes to Consolidated Financial Statements".

Extraordinary Gain. During the three months ended March 31, 2002, we recorded an extraordinary gain of $8.5 million related to the early retirement of our subordinated promissory notes and the repurchase of the beneficial conversion feature associated with these subordinated promissory notes. See Note 8 of the accompanying "Notes to Consolidated Financial Statements".

Cumulative Effect of a Change in Accounting Principle. On January 1, 2002, we adopted Statement of Financial Accounting Standard ("SFAS") No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 142 requires annual independent appraisals to be obtained for all reporting units, as defined in the statement, with values recorded for goodwill and other intangible assets. Based on the results of an independent appraisal obtained on the nutritional supplements business that we acquired in 1997, we recorded an impairment charge of $12.1 million to write-off the carrying value of the goodwill related to that business. See Note 6 of the accompanying "Notes to Consolidated Financial Statements".

Net (Loss) Income. Net loss for the three months ended March 31, 2002 was $31.5 million as compared to net income of $129,000 for the three months ended March 31, 2001. The basic and diluted net loss per common share for the three months ended March 31, 2002 was $4.66 compared to a basic and diluted income per common share of $0.02 for the three months ended March 31, 2001. See Note 10 of the accompanying "Notes to Consolidated Financial Statements".

Liquidity and Capital Resources

As of March 31, 2002, we had cash and cash equivalents of $22.4 million, a $29.6 million decrease from December 31, 2001. We have historically funded our business through operating cash flows, proceeds from borrowings and the issuance of equity securities, as well as contributions from IMT and affiliated companies of IMT. We used $4.7 million in cash for our operating activities during the three months ended March 31, 2002, which was due to a net decrease in accounts payable and accrued expenses of $3.7 million, an inventory increase of $1.4 million and $461,000 in losses adjusted for noncash expenses, offset by decreases in other current assets of $865,000. During the three months ended March 31, 2002, we used cash of $11.7 million for our investing activities, of which $8.1 million was used for the acquisition of IVC, $3.4 million was used for restructuring costs and additional acquisition costs related to the Unipath business, and $384,000 was used for capital expenditure purposes. During the three months ended March 31, 2002, we used cash of $13.0 million for financing activities, which primarily consisted of principal prepayments of $20.0 million on the subordinated

promissory notes, $10.0 million on the term loans with The Royal Bank of Scotland plc and $3.2 million on IVC's bank debt, net of a total of $20.9 million in proceeds received from issuance of preferred stock and stock option and warrant exercises. We also incurred $498,000 in financing costs related to various debt instruments. Working capital was $15.3 million as of March 31, 2002 compared to $21.0 million as of December 31, 2001.

On March 19, 2002, we acquired IVC, a manufacturer and distributor of vitamins and other nutritional supplements. We intend to consolidate our vitamin and nutritional supplement manufacturing at IVC and discontinue most of our outsourced manufacturing arrangements. The aggregate purchase price of IVC was approximately $27.3 million, which consisted of $5.6 million in cash representing $2.50 for each outstanding share of IVC's common stock, fully-vested stock options to purchase an aggregate of 115,744 shares of our common stock with an aggregate fair value of $1.3 million, approximately $1.6 million in estimated costs to exit certain activities of IVC, primarily severance costs, $17.4 million in assumed debt, including capital leases, and approximately $1.4 million in estimated direct acquisition costs. The acquisition was funded by our existing cash. Since the acquisition of IVC, we have made principal payments and prepayments on IVC's debt of $3.2 million. Of the remaining $14.2 million of IVC debt outstanding as of March 31, 2002, $6.9 million related to a credit agreement with Congress Financial Corporation ("Congress"), a subsidiary of First Union Corporation, and $7.3 million related to various notes payable and capital leases. Under the credit agreement with Congress, as amended, IVC can borrow up to $15.0 million under a revolving credit commitment and $4.2 million

under a term loan commitment, subject to borrowing base limitations, as defined in the agreement. The loans with Congress mature on October 16, 2003. Borrowings under the revolving credit commitment and the term loan bear interest at either 1.50% above the bank's prime rate or, at IVC's option, at 3.75% above the Adjusted Eurodollar Rate used by the bank. The notes are collateralized by substantially all of IVC's assets. The credit agreement with Congress requires IVC to maintain minimum tangible net worth and contains various restrictions customary in such financial arrangement, including limitations on the payment of cash dividends. IVC's other notes payable and capital leases mature on various dates through July 2008.

On December 20, 2001, one of our wholly-owned subsidiaries entered into a series of credit agreements (the "RBS Credit Agreements") with The Royal Bank of Scotland plc and related entities for credit facilities in the aggregate amount of $70.0 million, which were amended during the three months ended March 31, 2002. The RBS Credit Agreements consisted of various term loans aggregating $62.5 million, of which $10.0 million were denominated in Japanese Yen, and a $7.5 million multicurrency revolving line of credit. The proceeds of the term loans were used to finance a portion of the cash used to acquire the Unipath business. In March 2002, in connection with the amendments to the RBS Credit Agreements, we elected to make a $10.0 million principal prepayment on the senior term loans which therefore had a balance of $42.2 million as of March 31, 2002. The total outstanding loan balance under the RBS Credit Agreements as of March 31, 2002 was $52.3 million, including capitalized interest, as discussed below. The revolving line of credit is designated for use to cover certain of our liabilities and future foreign exchange contracts. As of March 31, 2002, there were no outstanding borrowings against the revolving line of credit. We and certain of our subsidiaries are the guarantors of all obligations due under the RBS Credit Agreements. Borrowings under the RBS Credit Agreements are secured by the stock of our European subsidiaries, our intellectual property rights and the assets of our business in the United States. We must make mandatory prepayments on the loans under the RBS Credit Agreements if we meet certain cash flow thresholds, collect insurance proceeds in excess of certain thresholds, receive payments and sell assets not in the ordinary course of our business or upon a sale or change of control of our company. The per annum interest rate on the loans is the London Interbank Offered Rate ("LIBOR") plus a spread from 1.50% to 3.50% (and an additional 2.00% in case of default), depending on the type of loan (senior or junior) and the interest period. On the loans in which the spread may vary, the spread depends on the ratio of our total debt to earnings before interest expense, taxes, depreciation and amortization ("EBITDA"). Interest at

4.00% per annum is capitalized on the junior loan which, including such capitalized interest, had a principal balance of $10.1 million at March 31, 2002. Capitalized interest may be paid upon agreement with the lender of our senior debt. The amount of capitalized interest as of March 31, 2002, was $109,000. In February 2002, we entered into an interest rate swap agreement with the bank, which applies to $34.8 to $41.7 million of the term loans that are denominated in U.S. Dollars, depending upon the interest period, and protects both parties against fluctuations in the LIBOR rate. Under the interest rate swap agreement, the LIBOR rate is set at a minimum of 3.36% and a maximum of 5.00%. Through June 30, 2002, the LIBOR rate under the interest rate swap agreement is set at 3.36%. Under the RBS Credit Agreements, as amended, we must comply with various financial and nonfinancial covenants starting in the second quarter of 2002. The primary financial covenants pertain to, among other things, interest coverage, cash flow coverage, leverage and EBITDA. Failure to comply with these covenants may have a material adverse impact on our financial condition.

On March 6, 2002, we prepaid our then outstanding subordinated promissory notes ("Subordinated Notes") having an aggregate principal amount of $20,000,000 and related accrued interest of $568,000 using the proceeds from the issuance of series A convertible preferred stock ("Series A Preferred Stock"). The original maturity date of the Subordinated Notes was April 1, 2002, with an extension option, and interest accrued at 12% per annum, or 18% if and when maturity date was extended. The Subordinated Notes were convertible into shares of our Series A Preferred Stock at the option of the holder.

During 1999, our subsidiary CDIL financed the purchase of one of the buildings that houses its manufacturing activities through a mortgage loan (the "CDIL Mortgage") with the seller. The outstanding balance of the CDIL Mortgage was $176,000 as of March 31, 2002. The CDIL Mortgage bears interest at 6% and is payable semiannually through 2003.

Our subsidiary Orgenics had bank debt balances totaling $153,000 as of March 31, 2002. Orgenics' bank debt is collaterized by certain of Orgenics' assets. The notes bear interest at various rates ranging from 3.43% to 4.25% and are payable on various dates through 2003.

In March 2002, we sold to private investors 531,913 shares of our Series A Preferred Stock at $39.01 per share for gross proceeds of $20.75 million for purposes of prepaying the $20.0 million Subordinated Notes and related accrued interest. The terms of these shares of Series A Preferred Stock are the same as those shares issued in December 2001. Each share of Series A Preferred Stock accrues dividends on a quarterly basis at $2.10 per annum, but only on those days when the closing price of our company's common stock is less than $15. As our company's stock price did not close below $15 following the issuance of the Series A Preferred Stock, no dividends were recorded during the three months ended March 31, 2002. Dividends accrued are payable only if declared by the board of directors. Until December 31, 2003, accrued dividends, if any, must be paid in our company's common stock. The number of shares of common stock to be issued in payment of any accrued dividends is equal to such number as is determined by dividing the aggregate amount of the accrued dividend then payable by the

greater of (i) $15 and (ii) the average market price during the 30 trading day period immediately preceding the date such dividend is declared. Thereafter, we have the option to pay dividends in cash or common stock. The number of shares of common stock to be issued upon any voluntary conversion of one share of Series A Preferred Stock is equal to such number as is determined by dividing $30 by the conversion price in effect at the time of conversion. The conversion price was initially $15 and is subject to adjustment. The effective purchase price for the shares of common stock underlying the Series A Preferred Stock issued in March 2002 represented a $2.70 (or 12%) discount to the fair value of our common stock on the issuance date. Starting on December 20, 2003, we may convert the Series A Preferred Stock into common stock in the event that the average closing price of our common stock exceeds $20 for any consecutive 30 trading day period. The Series A Preferred Stock may be redeemed upon a vote by the holders of at least two-thirds of the outstanding Series A

Preferred Stock on or after June 30, 2011. The redemption price per share of Series A Preferred Stock will be equal to $30 plus a premium calculated at 5% per annum from the date of issuance.

As of December 31, 2001, we had approximately $24.8 million of foreign net operating loss carryforwards. These losses are available to reduce foreign taxable income, if any, in future years. We have recorded a valuation allowance against the portion of the deferred tax assets related to foreign net operating losses and other foreign deferred tax assets to reflect uncertainties that might affect the realization of the deferred tax assets, as these assets can only be realized via profitable foreign operations.

Based on outstanding debt and other commitments as of March 31, 2002, we will be required to use approximately $11.7 million in cash over the next 12 months to meet debt maturities (approximately $6.9 million), minimum lease payments (approximately $3.7 million) and capital expenditure commitments (approximately $1.1 million). Based upon our current operating plans and business conditions, we believe that our existing capital resources and credit facilities will be adequate to fund our operations, including these outstanding debt and other commitments, for at least the next 12 months. We cannot be certain, however, that our underlying assumed levels of revenues and expenses will be realized. In addition, we may expand our research and development of, and may pursue the acquisition of, new products and technologies, whether through licensing arrangements, business acquisitions, or otherwise. If we decide to pursue such activities or if our operating results fail to meet our expectations, we could be required to seek additional funding through public or private financings or other arrangements. In such event, adequate funds may not be available when needed, or, if available, may not be on acceptable terms, which could have a negative effect on our business and results of operations. In addition, if we raise additional funds by issuing equity or convertible securities, dilution to then existing stockholders may result.

Critical Accounting Policies

The consolidated financial statements included in this quarterly report on Form 10-Q are prepared in accordance with accounting principles generally accepted in the United States. The accounting policies discussed below are considered by our management to be critical to an understanding of our financial statements because their application depends on management's judgment, with financial reporting results relying on estimations and assumptions about the effect of matters that are inherently uncertain. Specific risks for these critical accounting policies are described in the following paragraphs. For all of these policies, management cautions that future events rarely develop exactly as forecast and the best estimates routinely require adjustment. In addition, the "Notes to Consolidated Financial Statements" included in our annual report on Form 10K, as amended, for the year ended December 31, 2001 include a comprehensive summary of the significant accounting policies and methods used in the preparation of our consolidated financial statements.

Revenue Recognition

We recognize revenue in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 101 and its related amendments (collectively, "SAB No. 101"). SAB No. 101 requires that four basic criteria be met before revenue can be recognized: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed and determinable; and (4) collection is reasonably assured.

The majority of our revenues are derived from product sales. We recognize revenue upon product shipment to third-party customers, at which time title is transferred, less a reserve for estimated product returns and allowances. Determination of the reserve for estimated product returns and allowances is based on our management's analyses and judgments regarding certain conditions, as discussed below in the critical accounting policy "Use of Estimates for Sales Returns and Other

Allowances and Allowance for Doubtful Accounts." Should future changes in conditions prove management's conclusions and judgments on previous analyses to be incorrect, revenue recognized for any reporting period could be adversely affected.

Since the acquisition of the Unipath business in late December 2001, we also receive license and royalty revenue from agreements with third-parties licensees. Revenue from fixed fee license and royalty agreements are recognized on a straight-line basis over the obligation period of the related license agreements. License and royalty fees that are calculated based on the licensees' sales are recognized upon receipt of the license or royalty payments because we would not be able to determine such fees until such time.

Use of Estimates for Sales Returns and Other Allowances and Allowance for Doubtful Accounts

Sales arrangements with customers for our products generally require us to accept product returns. From time to time, we also enter into sales incentive arrangements with our customers, which generally reduce the sale prices of our products. Against product revenue recognized in any reporting period, we must establish allowances for potential future product returns and claims resulting from our sales incentive arrangements. Calculation of these allowances requires significant judgments and estimates. When evaluating the adequacy of the sales returns and other allowances, our management analyzes historical returns, current economic trends, and changes in customer demand and acceptance of our products. Material differences in the amount and timing of our product revenue for any reporting period may result if changes in conditions arise that would require management to make different judgments or utilize different estimates. Our provision for sales returns and other allowances related to sales incentive arrrangements amounted to approximately $7.7 million for the three months ended March 31, 2002.

Similarly, our management must make estimates of the uncollectibility of our accounts receivable balances. When evaluating the adequacy of the allowance for doubtful accounts, management analyzes specific accounts receivable balances, historical bad debts, customer concentrations, customer credit-worthiness, current economic trends and changes in our customer payment terms. Our accounts receivable balance was $27.1 million, net of an allowance for doubtful accounts of $1.3 million as of March 31, 2002.

Valuation of Goodwill and Other Long-Lived and Intangible Assets

Our long-lived assets include property, plant and equipment, goodwill and other intangible assets. As of March 31, 2002, the balances of property, plant and equipment, goodwill and other intangible assets, net of accumulated depreciation and amortization, were $42.6 million, $72.4 million and $61.9 million, respectively. For purposes of determining whether there are any impairment losses, our management has historically examined the carrying value of our identifiable long-lived tangible and intangible assets and goodwill when indicators of impairment are present. Effective January 1, 2002, SFAS No. 142 requires that independent impairment reviews be obtained on the carrying values of all goodwill on an annual basis. For all long-lived tangible and intangible assets and goodwill, if an impairment loss is identified based on the fair value of the asset, such loss would be charged to expense in the period we identify the impairment.

Valuation of Goodwill

During the three months ended March 31, 2002, we obtained an independent review on the carrying value of our existing goodwill in accordance with SFAS No. 142 which provides specific guidance for determining and measuring impairment of goodwill. Based upon the results of the review, we recorded an impairment charge of $12.1 million, representing the remaining goodwill related to our reporting unit that comprises the nutritional supplement lines we acquired in 1997. This amount

represented the excess of the carrying value over the fair value of such asset. The fair value was determined using a combination of the income approach and the market approach of valuing a business. The income approach valued the business by discounting projected future cash flows and the market approach valued the security underlying the business by comparing it to those of similar businesses. The most significant facts and circumstances that led to the conclusion of this impairment were (a) future cash flows from these nutritional supplement lines are expected to be reduced, (b) selling, general and administrative expenses relating to these nutritional supplement lines are forecasted to increase as a percentage of sales, and (c) this nutritional supplements business is experiencing a larger percentage decline in revenues than most of the comparable businesses of other companies. Because future cash flows and operating results used in the independent review are based on management's projections and assumptions, future events can cause actual results to differ from those projections. In such event, the full impairment charge of $12.1 million taken during the three months ended March 31, 2002 may not be justified.

Valuation of Other Long-Lived Tangible and Intangible Assets

Factors we generally consider important which could trigger an impairment review on the carrying value of other long-lived tangible and intangible assets include the following: (1) significant underperformance relative to expected historical or projected future operating results; (2) significant changes in the manner of our use of the acquired assets or the strategy for our overall business; (3) underutilization of our tangible

assets; (4) discontinuance of product lines by ourselves or our customers; (5) significant negative industry or economic trends; (6) significant decline in our stock price for a sustained period; (7) significant decline in our market capitalization relative to net book value; and (8) goodwill impairment identified during an independent review under SFAS No. 142.

Because the independent appraisal of the fair value of the reporting unit underlying our nutritional supplements business indicated an impairment of goodwill related to that reporting unit, as discussed above, we proceeded to also obtain an independent impairment review of the carrying value assigned to related trademarks and brand names. The results of this review also indicated an impairment of the carrying value of such trademarks and brand names because the full carrying amount of these intangible assets was not expected to be recoverable and exceeded its fair value. The carrying amount of these intangible assets was not recoverable because it exceeded the sum of the undiscounted cash flows expected to result from the use and eventual disposition of these assets. The fair value of these intangible assets was determined using a combination of the discounted cash flow approach and the relief from royalty approach, the latter of which valued the brand names as if they were licensed from a third party. Based on these results, we recorded another impairment charge of $12.7 million to write-off a portion of the carrying value of these trademarks and brand names during the three months ended March 31, 2002. The remaining carrying value of these intangible assets was $4.2 million at March 31, 2002, which is being amortized over the assets remaining useful lives of 20 years. The impairment was measured partly based on a projected discounted cash flow method using a discount rate determined by our management to be commensurate with the risk inherent in our current business model. Although we believe that the remaining carrying value of our long-lived tangible and intangible assets were realizable as of March 31, 2002, future events could cause us to conclude otherwise.

Accounting for Income Taxes

As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our actual current tax exposure and assessing temporary differences resulting from differing treatment of items, such as reserves and accruals and lives assigned to long-lived and intangible assets, for tax and accounting purposes. These differences result in deferred tax assets and liabilities. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and

to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within our tax provision.

Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have recorded a valuation allowance of $12.3 million as of December 31, 2001, due to uncertainties related to the future benefits from our deferred tax assets, primarily consisting of certain foreign net operating losses and tax credits, before these losses and credits expire. The valuation allowance is based on our estimates of taxable income by jurisdiction in which we operate and the period over which our deferred tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods, we may need to establish an additional valuation allowance which could materially impact our tax provision.

Legal Contingencies

Because of the nature of our business, we may from time to time be subject to consumer product claims or various other lawsuits arising in the ordinary course of our business and we expect this will continue to be the case in the future. These lawsuits generally seek damages, sometimes in substantial amounts, for personal injuries or other commercial claims. In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties, which can be expensive and can result in counterclaims against us. We are currently involved in certain legal proceedings, as discussed in "Part II, Item 1. Legal Proceedings" in this quarterly report on Form 10-Q. We do not accrue for potential losses on legal proceedings where our company is the defendant when we are not able to quantify our potential liability, if any, due to uncertainty as to the nature, extent and validity of the claims against us, uncertainty as to the nature and extent of the damages or other relief sought by the plaintiff and the complexity of the issues involved. Our potential liability, if any, in a particular case may become quantifiable as the case progresses, which will require us to begin accruing for the expected loss.

In addition, in Part II, Item 1 of this report, we have reported on certain legal proceedings as to which we do not believe a final ruling against us could have a material adverse impact on our financial position and operations. To the extent that unanticipated facts or circumstances arise that cause us to change this assessment with respect to any matter, our future results of operations and financial position could be materially affected.

Recently Issued Accounting Standards

In June 2001, the Financial Accounting Standards Board ("FASB") issued SFAS No. 142, which addresses changes in the financial accounting and reporting for acquired goodwill and other intangible assets with indefinite lives. Effective January 1, 2002, all existing acquired goodwill and other intangible assets with indefinite lives are no longer amortized to expense, with early adoption required for all goodwill and other intangible assets with indefinite lives acquired subsequent to June 30, 2001. The statement also provides specific guidance for determining and measuring impairment of all goodwill and other intangible assets. We recorded goodwill amortization of approximately $151,000 for the three months ended March 31, 2001. At March 31, 2002, the total amount of goodwill and other intangible assets with indefinite lives affected by this statement was $98.1 million, which was all acquired subsequent to June 30, 2001. Also, at the adoption of SFAS No. 142, we recorded a goodwill impairment charge of $12.1 million during the three months ended March 31, 2002. See Note 6 of the accompanying "Notes to Consolidated Financial Statements".

In August 2001, the FASB issued SFAS No. 144, which addresses financial accounting and reporting for the impairment or disposal of long-lived assets. This statement requires that a long-lived

asset to be abandoned, exchanged for a similar productive asset, or distributed to owners in a spin-off be considered held and used until it is disposed of. The changes in this statement require that one accounting model be used for long-lived assets to be disposed of by sale, whether previously held and used or newly acquired, and broaden the presentation of discontinued operations to include more disposal transactions. SFAS No. 144 also provides guidance for determining and measuring impairment of long-lived and intangible assets, which do not materially differ from previous guidance. The provisions of this statement are effective for financial statements issued for fiscal years beginning after December 15, 2001 and interim periods within those fiscal years, with early adoption encouraged. The provisions of this statement generally are to be applied prospectively. During the three months ended March 31, 2002, we recorded an impairment charge to our carrying value of certain trademarks and brand names of $12.7 million in accordance with SFAS No. 144. See Note 6 of the accompanying "Notes to Consolidated Financial Statements".

In November 2001, the EITF issued EITF Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer or a Reseller of the Vendor's Products*. EITF Issue No. 01-9 establishes accounting and reporting standards for vendor consideration to any purchasers of the vendor's products at any point along the distribution chain, regardless of whether the purchaser receiving the consideration is a direct customer. We offer certain sales incentives that fall within the scope of EITF Issue No. 01-9, such as free goods, slotting fees and cooperative advertising, to some of our customers. We adopted the provisions of this consensus in 2002, the effect of which was a net reclassification of $960,000 and $327,000 from sales and marketing expenses and cost of sales to net product sales during the three months ended March 31, 2002 and 2001, respectively.

Certain Factors Affecting Future Results

There are various risks, including those described below, which may materially impact your investment in our company or may in the future, and, in some cases already do, materially affect us and our business, financial condition and results of operations. You should consider carefully these factors, as well as the risk factors identified from time to time in our periodic filings with the Securities and Exchange Commission, in connection with your investment in our securities. This section includes or refers to certain forward-looking statements; you should read the explanation of the qualifications and limitations on such forward-looking statements on pages 2 and 46 of this report.

Risks Related to the Split-Off

On November 21, 2001, we were split-off from IMT and became an independent, publicly owned company as part of a transaction by which IMT was acquired by Johnson & Johnson. Prior to that time, we had been a majority owned subsidiary of IMT, and the businesses that we acquired in connection with the restructuring that preceded the split-off represented approximately 20% of IMT's net product sales during the calendar quarter concluded immediately prior to the split-off. We continue to face a unique set of challenges and risks arising out of the split-off.

Our businesses will face challenges as part of a stand-alone company that we did not experience as part of IMT.

As an independent, publicly owned company, we now face new issues and challenges that we did not experience when we were part of IMT. Examples of potential issues include:

our inability to rely on the long-term financial strength of IMT;

our inability to rely on the earnings, cash flow, assets and goodwill of IMT's diabetes business;

our inability to rely on the experience and business relationships of some personnel who remained with IMT;

greater difficulty in obtaining financing on terms satisfactory to us, if needed;

greater difficulty in obtaining and maintaining insurance on terms that are acceptable to us;

increased costs of hiring and retaining employees in departments previously shared by all the businesses of IMT, including the legal, risk management, tax, treasury, human resources and public relations departments; and

generally increased overhead and administrative costs as a result of establishing a stand-alone company.

We may not resolve these issues or overcome these challenges. As a result, we may not succeed in generating and expanding customer relationships, containing costs and expenses and enhancing our business. In addition, competitive and market factors specific to the consumer diagnostics, vitamins and nutritional supplements and clinical diagnostics industries will more significantly impact our smaller, less diversified company.

Our businesses traditionally relied on IMT for financial assistance and may have difficulty with liquidity and capital requirements without this assistance.

Prior to the split-off, our businesses relied on the earnings, assets and cash flow of IMT for liquidity, capital requirements and administrative services. In the past, when the liquidity needs of our businesses exceeded their cash flow, IMT provided the necessary funds. As a result of the split-off, we can no longer rely on IMT for financial assistance. Accordingly, if we are unable to generate sufficient cash flow or borrow sufficient amounts under our credit facilities to fund our working capital needs and to pay our debts, we will need to obtain additional financing. We do not know if we can obtain additional financing or if the terms of any required financing will be acceptable to us. If we are unable to fund our working capital needs and additional growth through our existing credit facilities, cash flow, or additional financing, or if additional financing is not available under acceptable terms to us, our business prospects, results of operations, cash flow and future growth will be negatively affected.

Our historical financial information may not be representative of our results as a separate company.

The historical financial information relating to the three months ended March 31, 2001 included in this quarterly report on Form 10-Q reports on a time period prior to the split-off and reflects the operating history of our businesses when they were a part of IMT. As a result, the financial information may not reflect what our results of operations, financial position and cash flows would have been had we been a separate, stand-alone company during that period. This financial information also may not reflect what our results of operations, financial position and cash flows will be in the future. This is not only related to the various risks associated with the fact that we have not been a stand-alone company for a long period of time, but also because:

various adjustments and allocations were made to the financial statements for the three months ended March 31, 2001 because IMT did not account for us as a single stand-alone business for that period presented; and

the information does not reflect many significant changes that occurred in our financial condition, capital structure and operations as a result of our separation from IMT.

The adjustments and allocations we made in preparing our financial information for the three months ended March 31, 2001 may not appropriately reflect our operations during that period as if we had operated as a stand-alone company.

The change of some personnel in our company in conjunction with the split-off may impact our business.

Some of IMT's personnel became our initial employees, while others did not. In particular, certain significant employees of IMT who were engaged primarily in the diabetes care products business remained with that business. In addition, some members of IMT's management who worked substantially for IMT's diabetes care products business became our employees. Finally, some IMT personnel who provided services beneficial to our businesses through their work in IMT's accounting, sales, marketing, operations, quality assurance, regulatory compliance and other areas did not become part of our company after the split-off or, in certain cases, their services may only be available to us on a transitional basis for a short period of time. The loss of certain significant employees, the transition of personnel from IMT's diabetes business to our company and the loss of other IMT personnel who will not become our employees may impact or disrupt our sales and marketing activities, our research and development efforts or our administrative functions.

Our stock price may fluctuate significantly and stockholders who buy or sell our common stock may lose all or part of the value of their investment, depending on the price of our common stock from time to time.

Our common stock has only been listed on the American Stock Exchange since November 23, 2001. Because we have been listed for only a short period of time, we cannot assure you that an active trading market in our common stock will develop or be sustained in the future. Our common stock may experience volatility until trading values become established. As a result, it could be difficult to make purchases or sales of our common stock in the market at any particular time.

IMT stockholders immediately prior to the split-off became stockholders of our company immediately after the split-off. Some stockholders who received our common stock in the split-off may decide that they do not want to maintain an investment in a company involved primarily in consumer and clinical diagnostic products and vitamins and nutritional supplements or in a public company that has a limited track record as a stand-alone company. If these stockholders decide to sell all or some of their shares or if the market perceives that those sales could occur, the trading value of your shares may decline. In addition, because we will be a smaller and less diversified company than IMT, market analysts and the investment community may not follow our common stock as closely as they have followed IMT common stock in the past. If there is only a limited following by market analysts or the investment community, the amount of market activity in our common stock may be reduced, making it more difficult for you to sell your shares.

In addition, our share price may be volatile due to our operating results, as well as factors beyond our control. It is possible that in some future periods the results of our operations will be below the expectations of the public market. In any such event, the market price of our common stock could decline. Furthermore, the stock market may experience significant price and volume fluctuations, which may affect the market price of our common stock for reasons unrelated to our operating performance. The market price of our common stock may be highly volatile and may be affected by factors such as:

- our quarterly and annual operating results, including our failure to meet the performance estimates of securities analysts;
- changes in financial estimates of our revenues and operating results or buy/sell recommendations by securities analysts;
- the timing of announcements by us or our competitors of significant products, contracts or acquisitions or publicity regarding actual or potential results or performance thereof;
- changes in general conditions in the economy, the financial markets or the health care industry;
- government regulation in the health care industry;
- changes in other areas such as tax laws;

sales of substantial amounts of common stock or the perception that such sales could occur;

changes in investor perception of our industry, our businesses or our prospects; or

other developments affecting us or our competitors.

We are obligated to indemnify IMT and others for liabilities which could require us to pay IMT amounts that we may not have.

The restructuring agreement, post-closing covenants agreement and related agreements entered into in connection with the split-off and merger transaction with Johnson & Johnson provide that we will indemnify IMT and other related persons for specified liabilities related to our businesses, statements in the proxy statement/prospectus issued in connection with the split-off and merger about

our businesses and breaches of our obligations under the restructuring agreement, post-closing covenants agreement and related agreements. We are also required to indemnify IMT for losses, if any, arising from the failure to amend some outstanding warrants for the purchase of IMT common stock.

In addition, under our tax allocation agreement with IMT and Johnson & Johnson, we will indemnify Johnson & Johnson and IMT for any unpaid tax liabilities attributable to the pre-split-off operation of our consumer diagnostics, vitamins and nutritional supplements and clinical diagnostics businesses.

While no claims for indemnification have yet been made (and may never be made), we are unable to predict the amount, if any, that may be required for us to satisfy our indemnification obligations under these agreements. However, if claims are made for indemnification and we are liable for such claims, the amount could be substantial. In such an event, we may not have sufficient funds available to satisfy our potential indemnification obligations. In addition, we may be unable to obtain the funds on terms satisfactory to us, if at all. If we are unable to obtain the necessary funds, we will need to consider other alternatives, including sales of assets, to raise necessary funds.

Risks Related to our Business

Our business has substantial indebtedness which could result in adverse consequences for us.

As of March 31, 2002, we had approximately $66.7 million of outstanding indebtedness under our credit facilities and other debt-related instruments. Our substantial level of debt affects our future operations in several important ways, including the following:

our ability to obtain additional financing may be impaired;

our flexibility to adjust to market conditions is limited, leaving us vulnerable in a downturn in general economic conditions or in our business and less able to plan for, or react to, changes in our business and the industries in which we operate;

we may need to use a large portion of our cash flow from operations to pay principal and interest on our indebtedness, which would reduce the amount of cash available to finance our operations and other business activities and may require us, in order to meet our debt service obligations, to delay or reduce capital expenditures or the introduction of new products and/or forego business opportunities including acquisitions, research and development projects or product design enhancements; and

we may be at a competitive disadvantage compared to our competitors that have less debt.

Furthermore, there can be no assurance that our cash flow from operations and capital resources will be sufficient to pay our indebtedness. If our cash flow and capital resources prove inadequate we could face substantial liquidity problems and might be required to dispose of material

assets or operations, restructure or refinance our debt or seek additional equity capital.

Additionally, the agreements governing our indebtedness subject us to various restrictions on our ability to engage in certain activities, including, among other things, our ability to:

incur additional indebtedness;

acquire other businesses;

make capital or finance lease expenditures; and

dispose of assets.

These restrictions may limit our ability to pursue business opportunities or strategies that we would otherwise consider to be in the best interests of our stockholders.

Our credit facilities contain certain financial covenants and other conditions that we may not satisfy which, if not satisfied, could result in the acceleration of the amounts due under our credit facilities and the limitation of our ability to borrow additional funds in the future.

As of March 31, 2002, we had approximately $59.3 million of outstanding indebtedness under our various credit facilities, substantially all of which were owed to The Royal Bank of Scotland plc and related entities and Congress Financial Corporation, IVC's lender. The agreements governing these various credit facilities subject us to various financial and other covenants with which we must comply on an ongoing or periodic basis. These include covenants pertaining to interest coverage, cash flow coverage, leverage and EBITDA. If we violate any of these covenants, there may be a material adverse effect on us. Most notably, our outstanding debt under one or more of our credit facilities could become immediately due and our ability to borrow additional funds in the future may be limited. Additionally, under the terms of our credit facilities with The Royal Bank of Scotland plc and related entities, if either Ron Zwanziger or David Scott ceases to be a member of our board of directors, the full amount of our indebtedness under these credit facilities will accelerate. Mr. Zwanziger and Dr. Scott, both of whom are executive officers of our company, are currently serving on our board of directors; however, there is no assurance that they will continue to do so.

Rising interest rates would increase our interest costs and reduce our earnings.

We currently have, and may incur more, indebtedness that bears interest at variable rates. Accordingly, if interest rates increase, so will our interest costs, which would adversely affect our earnings, cash flow and our ability to service debt.

Non-competition obligations and other restrictions will limit our ability to take full advantage of our management team, the technology we own or license and our research and development capabilities.

Members of our management team have had significant experience in the diabetes field, technology we own or license may have potential applications to this field, and our research and development capabilities could be applied to this field. In conjunction with the split-off and merger, however, we agreed in the post-closing covenants agreement not to compete with IMT and Johnson & Johnson in the field of diabetes. In addition, Ron Zwanziger, our Chairman, President and Chief Executive Officer, and two of our senior scientists, Dr. David Scott and Dr. Jerry McAleer, have entered into consulting agreements with IMT that impose similar obligations. Further, the license agreement prevents us from using any of the licensed technology in the field of diabetes. As a result of these restrictions, we cannot pursue opportunities in the field of diabetes.

Our acquisitions of the Unipath business and IVC may not be profitable or successfully integrated and will result in significant charges against earnings.

On December 20, 2001, we acquired the Unipath business from Unilever and certain affiliated entities. On March 19, 2002, we acquired IVC. The value of the Unipath business and IVC to us may not be greater than or equal to their purchase prices. Further, we cannot guarantee that we will realize any of the benefits or strategic objectives we are seeking to obtain by acquiring the Unipath business or IVC. In connection with accounting for the acquisition of the Unipath business, we have recorded a significant amount of intangible assets. Under Statement of Financial Accounting Standards ("SFAS") No. 142, *Goodwill and Other Intangible Assets*, we must assess, at least annually and potentially more frequently, whether the value of goodwill and other intangible assets has been impaired. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings which could materially adversely affect our results of operations in future periods. In addition, in connection with the acquisition of the Unipath business, the portion of the purchase price allocated to in-process research and development projects that had not reached technological feasibility was charged to expense during the fourth quarter of 2001. To bring these projects to technological feasibility,

high-risk development and testing issues will need to be resolved that will require substantial additional effort and expense.

We could experience significant manufacturing delays, disruptions to our ongoing research and development and increased production costs if Unilever is unable to successfully assign or sublease to us the lease for the primary operating facility of the Unipath business which is located in Bedford, England.

The primary operating facility of the Unipath business that we acquired from Unilever is located in Bedford, England. The Bedford facility is a multi-purpose facility that is registered with the United States Food and Drug Administration ("FDA"), contains state-of-the-art research laboratories and is equipped with specialized manufacturing equipment. This facility currently provides the manufacturing for the Unipath business that we recently acquired, serves as our research and development center and serves as the administrative center for our European operations. We are currently using the Bedford facility pursuant to an agreement with Unilever entered into in connection with our acquisition of the Unipath business. Unilever currently leases this facility from a third party landlord. Pursuant to the terms of Unilever's lease, however, Unilever is not permitted to assign the lease or sublet the Bedford facility without obtaining the prior written consent of the landlord (which consent may not be unreasonably withheld). The landlord has recently indicated that it will not consent to an assignment of the lease to us but will consider a sublease. The terms of our acquisition of the Unipath business obligate Unilever to use reasonable endeavors to obtain the landlord's consent to assignment or to a sublease of the facility and, if necessary, to pursue the assignment or sublease through the courts. There are no assurances that Unilever will be successful in obtaining the landlord's consent to assignment of the lease to us or to a sublease to us. If Unilever is unable to successfully acquire such consent or otherwise enable us to realize the benefit of its lease of the Bedford facility, we may be forced to renegotiate a lease of the Bedford facility on substantially less favorable terms or seek alternative means of producing our products, conducting our research and housing our European administrative staff. In either case, we may experience manufacturing delays and disruptions to our ongoing research and development while we are resolving these issues and increased production costs in the future. Additionally, there are no assurances that we will be able to renegotiate a lease for the Bedford facility on terms that are acceptable to us or find an acceptable replacement for this facility. Any one or more of these events may have a material adverse effect on us.

If we choose to acquire or invest in new and complementary businesses, products or technologies instead of developing them ourselves, these acquisitions or investments could disrupt our business and, depending on how we finance these acquisitions or investments, could result in significant dilution to our existing stockholders.

Our success depends in part on our ability to continually enhance and broaden our product offerings in response to changing technologies, customer demands and competitive pressures. Accordingly, from time to time we may seek to acquire or invest in complementary businesses, products or technologies instead of developing them ourselves. Acquisitions and investments involve numerous risks, including:

- the inability to complete the acquisition or investment;
- disruption of our ongoing businesses and diversion of management attention;
- difficulties in integrating the acquired entities, products or technologies;
- difficulties in operating the acquired business profitably;

the inability to achieve anticipated cost savings;

potential loss of key employees, particularly those of the acquired business;

difficulties in transitioning key customer, distributor and supplier relationships;

risks associated with entering markets in which we have no or limited prior experience; and

unanticipated costs.

In addition, any future acquisitions or investments may result in:

dilutive issuances of equity securities, which may be sold at a discount to market price;

use of significant amounts of cash;

the incurrence of debt;

the assumption of liabilities;

unfavorable financing terms;

large one-time expenses; and

the creation of certain intangible assets, including goodwill, the writedown of which may result in significant charges to earnings.

Any of these factors could materially harm our business or our operating results.

Manufacturing problems or delays could severely affect our business.

We produce our consumer products in our manufacturing facilities located in New Jersey and in Bedford, England and Galway, Ireland and our clinical diagnostic tests in our manufacturing facilities located in Bedford and in Yavne, Israel. Our production processes are complex and require specialized and expensive equipment. We rely on third parties to supply production materials and in some cases there may not be alternative sources immediately available. In addition, until we are able to consolidate manufacturing of our vitamins and nutritional supplements in our New Jersey manufacturing facilities, we will continue to rely, in part, upon third parties to manufacture these products. Any event impacting these facilities or our contract manufacturers or suppliers could delay or suspend shipments of products, or could result in the delivery of inferior products. Our revenues from the affected products would decline until such time as we were able to put in place alternative contract manufacturers or suppliers. Even though we carry business interruption insurance policies, we may suffer losses as a result of business interruptions that exceed the coverage available under our insurance policies.

If we fail to meet strict regulatory requirements, we could be required to pay fines or even close our facilities.

Our facilities and manufacturing techniques generally must conform to standards that are established by government agencies, including those of European governments, as well as the FDA. These regulatory agencies may conduct periodic inspections of our facilities to monitor our compliance with applicable regulatory standards. If a regulatory agency finds that we fail to comply with the appropriate regulatory standards, it

may impose fines on us or if such a regulatory agency determines that our non-compliance is severe, it may close our facilities. Any adverse action by an applicable regulatory agency could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands.

If we deliver products with defects, our credibility may be harmed, market acceptance of our products may decrease and we may be exposed to liability in excess of our product liability insurance coverage.

The manufacturing and marketing of consumer and clinical diagnostic products involve an inherent risk of product liability claims. In addition, our product development and production are extremely

complex and could expose our products to defects. Any defects could harm our credibility and decrease market acceptance of our products. In addition, our marketing of vitamins and nutritional supplements may cause us to be subjected to various product liability claims, including, among others, claims that the vitamins and nutritional supplements have inadequate warnings concerning side effects and interactions with other substances. Potential product liability claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of the policy. In the event that we are held liable for a claim for which we are not indemnified, or for damages exceeding the limits of our insurance coverage, that claim could materially damage our business and our financial condition.

Sales of the nutritional supplements that we sold prior to acquiring IVC have declined each year since 1998 due to the maturity of the market segments they serve and the age of that product line and we may experience further declines in sales of those products.

Sales of the nutritional products that we sold prior to acquiring IVC have declined each year since 1998 and we have budgeted for future sale declines for those products. We believe that those products have under-performed because they are, for the most part, aging brands with limited brand retention that face increasing private label competition. The age of this product line means that we are subject to future distribution loss for under-performing brands, while our opportunities for new distribution on the existing product lines are limited.

The vitamin and nutritional supplements market is subject to significant fluctuations based upon media attention and new developments.

Most growth in the vitamin and nutritional supplement industry is attributed to new products that generate attention in the marketplace. Positive media attention resulting from new scientific studies or announcements can spur rapid growth in individual segments of the market, and also impact individual brands. Conversely, news that challenges individual segments or products can have a negative impact on the industry overall as well as on sales of the challenged segments or products. Most of our vitamin and nutritional supplements products, including most of the vitamins and nutritional products that we acquired from IVC, serve well-established market segments and, absent unforeseen new developments or trends, are not expected to benefit from rapid growth. A few of the vitamin and nutritional products acquired with IVC are newer products that are more likely to be the subject of new scientific studies or announcements, which could be either positive or negative. News or other developments that challenges the safety or effectiveness of these products could negatively impact the profitability of our vitamin and nutritional supplements business.

Sales of our clinical diagnostics products could suffer if economic trends in the health care industry harm our niche market of small and medium sized laboratories.

Our Clearview® clinical diagnostic products are low cost alternatives to expensive and time consuming centralized testing marketed to point-of-care professionals. Orgenics sells clinical diagnostics products targeted at a niche market of small and medium sized decentralized laboratories in developing nations. To the extent that trends or changes in the health care industry favor economies of scale and centralized, automated laboratory testing, sales of our clinical diagnostics products could suffer.

Revenue from our clinical diagnostics business may decline in the future because trends in the overall market favor direct disease detection over immune response testing.

New technologies have made it possible to directly identify the presence of disease rather than detecting the presence of antibodies produced through an immune response. The trend of the overall market currently favors direct detection over antibody detection. Virus detection through nucleic acid testing, or NAT, is already mandatory for hepatitis C virus and other markers in France, Australia and certain other developed nations. We believe that the threat from direct detection technology in our

core market of small and medium sized decentralized laboratories, small blood banks, physicians and other point of care facilities, particularly in under developed nations, is several years away. However, this trend poses a risk to our core clinical diagnostics business in the long term.

We market our Orgenics clinical diagnostics products to small and medium sized customers in more than 90 countries at considerable cost that reduces the operating margins in our Orgenics clinical diagnostics business.

Because small and medium sized laboratories are the principal customers of our Orgenics clinical diagnostic products, we sell these products worldwide in order to maintain sufficient sales volume. Our Orgenics clinical diagnostics products are marketed in more than 90 countries, including many third world and developing nations where smaller laboratories are the norm, where more expensive technologies are not affordable and where infectious diseases are often more prevalent. This worldwide sales strategy is expensive and results in lower margins than would be possible if we could generate sufficient sales volume by operating in fewer markets.

We could suffer monetary damages, incur substantial costs or be prevented from using technologies important to our products as a result of a number of pending legal proceedings.

We are involved in various legal proceedings arising out of our consumer diagnostics, nutritional supplements and clinical diagnostics business. The current material legal proceedings are:

- a lawsuit by Abbott Laboratories against us and Princeton BioMeditech Corporation, which manufactured products for our consumer diagnostics business while it was part of IMT, claiming, among other things, that some of our products relating to pregnancy detection and ovulation prediction infringe patents to which Abbott asserts it is the exclusive licensee;

- a lawsuit by Becton, Dickinson and Company alleging that pregnancy and ovulation test kits that we sell, and which we will continue to sell through our consumer diagnostics business, infringe U.S. Patent No. 4,703,017;

- complaints by Intervention, Inc. against us, four of our private label customers, whom we are defending under agreement, and certain other parties alleging that under Section 17200 of the California Business and Professions Code the defendants' labeling on their home pregnancy tests is misleading as to the level of accuracy under certain conditions; and

- an action brought by 69 consumers in London alleging defects in our Persona contraceptive device leading to unwanted pregnancies.

Because the above claims each seek damages and reimbursement for costs and expenses without specific amounts, we are unable to assess the probable outcome of or potential liability arising from the lawsuits.

In connection with our split-off from IMT, we agreed to assume, to the extent permitted by law, and indemnify IMT for, its liabilities in these lawsuits together with any other liabilities arising out of the women's health, nutritional supplements and clinical diagnostics businesses before or after the split-off to the extent such liabilities are not otherwise retained by IMT. Through our acquisitions of the Unipath business and IVC we also assumed or acquired substantially all of the liabilities of those businesses. We are unable to assess the materiality or costs associated with these lawsuits at this time. We cannot assure you that these lawsuits or any future lawsuits relating to our businesses will not have a material adverse effect on us.

The profitability of our consumer products businesses may suffer if we are unable to establish and maintain close working relationships with our customers.

Our consumer products businesses rely to a great extent on close working relationships with our customers rather than long-term exclusive contractual arrangements. With the exception of certain customers of IVC, customers of our branded and private label consumer products

businesses purchase products through purchase orders only and are not obligated to make future purchases. The loss of a major customer or the failure to generate new accounts could dramatically reduce revenues or prevent us from achieving projected growth.

Retailer consolidation poses a threat to existing retailer relationships and can result in lost revenue.

Recent years have witnessed rapid consolidation within the mass retail industry. Drug store chains, grocery stores and mass merchandisers, the primary purchasers of our consumer diagnostic products and vitamins and nutritional supplements, have all been subject to this trend. Because these customers purchase through purchase orders, consolidation can interfere with existing retailer relationships, especially private label relationships, and result in the loss of major customers and significant revenue streams.

Our financial condition or results of operations may be adversely affected by international business risks.

A significant number of our employees, including sales, support and research and development personnel, are located outside of the United States. Conducting business outside of the United States is subject to numerous risks, including:

decreased liquidity resulting from longer accounts receivable collection cycles typical of foreign countries;

lower productivity resulting from difficulties managing our sales, support and research and development operations across many countries;

lost revenues resulting from difficulties associated with enforcing agreements and collecting receivables through foreign legal systems;

lost revenues resulting from the imposition by foreign governments of trade protection measures; and

higher cost of sales resulting from import or export licensing requirements.

Because our business relies heavily on foreign operations and, to a lesser extent, foreign sales, changes in foreign currency exchange rates and our ability to convert currencies may negatively affect our financial condition and results of operations.

Our business relies heavily on our foreign operations. Three of our manufacturing facilities are outside the United States, in Bedford, England, Galway, Ireland and Yavne, Israel. Orgenics has always made substantially all of its sales outside of the United States. Through our recent acquisitions of the Unipath business and IVC, we expect foreign sales to grow significantly. The Unipath business generated approximately 70% of its net product sales outside of the United States during 2001 and IVC generated almost 14% of its net product sales outside of the United States during its fiscal year ending July 31, 2001. Because of our foreign operations and foreign sales, we face exposure to movements in foreign currency exchange rates. Our primary exposures are related to the operations of our European and South American subsidiaries. These exposures may change over time as business practices evolve and could result in increased costs or reduced revenue and could impact actual cash flow.

Our Orgenics subsidiary is located in Israel, and its operations could be negatively affected due to military or political tensions in the Middle East.

Our wholly-owned subsidiary, Orgenics Ltd., which develops, manufactures and sells certain of our clinical diagnostic products, is incorporated under the laws of the State of Israel. The administrative offices and development and manufacturing operations of our Orgenics business are located in Yavne, Israel. Although most of Orgenics' sales currently are to customers outside of Israel, political, economic and military conditions in Israel could nevertheless directly affect its operations. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its Arab neighbors and a state of hostility, varying in degree and intensity, has led to security and economic problems for Israel. Despite its history of avoiding adverse effects, our Orgenics business could be adversely affected by any major hostilities involving Israel, including the current armed conflict with the Palestinian authority.

Intense competition could reduce our market share or limit our ability to increase market share, which could impair the sales of our products and harm our financial performance.

The medical products industry is rapidly evolving and developments are expected to continue at a rapid pace. Competition in this industry, which includes both our consumer diagnostics and clinical diagnostics businesses, is intense and expected to increase as new products and technologies become available and new competitors enter the market. Our competitors in the United States and abroad are numerous and include, among others, diagnostic testing and medical products companies, universities and other research institutions. Our future success depends upon our maintaining a competitive position in the development of products and technologies in our areas of focus. Competitors may be more successful in:

- developing technologies and products that are more effective than our products or that render our technologies or products obsolete or noncompetitive;
- obtaining patent protection or other intellectual property rights that would prevent us from developing our potential products; or
- obtaining regulatory approval for the commercialization of their products more rapidly or effectively than we are in doing so.

Also, the possibility of patent disputes with competitors holding foreign patent rights may limit or delay expansion possibilities for our consumer diagnostics business in certain foreign jurisdictions. In addition, many of our existing or potential competitors have or may have substantially greater research and development capabilities, clinical, manufacturing, regulatory and marketing experience and financial and managerial resources.

The market for the sale of vitamins and nutritional supplements is also highly competitive. This competition is based principally upon price, quality of products, customer service and marketing support. There are numerous companies in the vitamins and nutritional supplements industry selling products to retailers such as mass merchandisers, drug store chains, independent drug stores, supermarkets and health food stores. As most of these companies are privately held, we are unable to obtain the information necessary to assess precisely the size and success of these competitors. However, we believe that a number of our competitors, particularly manufacturers of nationally advertised brand name products, are substantially larger than we are and have greater financial resources.

The rights we rely upon to protect the intellectual property underlying our products may not be adequate, which could enable third parties to use our technology and would reduce our ability to compete in the market.

Our success will depend in part on our ability to develop or acquire commercially valuable patent rights and to protect our intellectual property. Our patent position is generally uncertain and involves complex legal and factual questions. The degree of future protection for our proprietary rights is uncertain.

The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

- the pending patent applications we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents;
- the claims of any patents which are issued may not provide meaningful protection;
- we may not be able to develop additional proprietary technologies that are patentable;

the patents licensed or issued to us or our customers may not provide a competitive advantage;

other companies may challenge patents licensed or issued to us or our customers;

patents issued to other companies may harm our ability to do business; and

other companies may design around technologies we have licensed or developed.

In addition to patents, we rely on a combination of trade secrets, nondisclosure agreements and other contractual provisions and technical measures to protect our intellectual property rights. Nevertheless, these measures may not be adequate to safeguard the technology underlying our products. If they do not protect our rights, third parties could use our technology and our ability to compete in the market would be reduced. In addition, employees, consultants and others who participate in the development of our products may breach their agreements with us regarding our intellectual property and we may not have adequate remedies for the breach. We also may not be able to effectively protect our intellectual property rights in some foreign countries. For a variety of reasons, we may decide not to file for patent, copyright or trademark protection or prosecute potential infringements of our patents. We also realize that our trade secrets may become known through other means not currently foreseen by us. Despite our efforts to protect our intellectual property, our competitors or customers may independently develop similar or alternative technologies or products that are equal or superior to our technology and products without infringing on any of our intellectual property rights or design around our proprietary technologies.

Claims by other companies that our products infringe on their proprietary rights could adversely affect our ability to sell our products and increase our costs.

Substantial litigation over intellectual property rights exists in both the consumer and clinical diagnostic industries. We expect that our products and products in these industries may increasingly be subject to third party infringement claims as the number of competitors grows and the functionality of products and technology in different industry segments overlaps. Third parties may currently have, or may eventually be issued, patents on which our products or technology may infringe. Any of these third parties might make a claim of infringement against us. Any litigation could result in the expenditure of significant financial resources and the diversion of management's time and resources. In addition, litigation in which we are accused of infringement may cause negative publicity, have an impact on prospective customers, cause product shipment delays, require us to develop non-infringing technology or enter into royalty or license agreements, which may not be available on acceptable terms, or at all. If a successful claim of infringement were made against us and we could not develop non-infringing

technology or license the infringed or similar technology on a timely and cost-effective basis, our revenue may decrease and we could be exposed to legal actions by our customers.

We have initiated, and may need to further initiate, lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive and, if we lose, could cause us to lose some of our intellectual property rights, which would reduce our ability to compete in the market.

We rely on patents to protect a portion of our intellectual property and our competitive position. In order to protect or enforce our patent rights, we may initiate patent litigation against third parties, such as infringement suits or interference proceedings. Litigation may be necessary to:

assert claims of infringement;

enforce our patents;

protect our trade secrets or know-how; or

determine the enforceability, scope and validity of the proprietary rights of others.

Currently, we have initiated a number of lawsuits against competitors who we believe to be selling products that infringe our proprietary rights. These current lawsuits and any other lawsuits that we initiate could be expensive, take significant time and divert management's attention from other business concerns. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third parties to assert claims against us. Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in our industry are generally uncertain. We may not prevail in any of these suits and the damages or other remedies awarded, if any, may not be commercially valuable. During the course of these suits, there may be public announcements of the results of hearings, motions and other interim proceedings or developments in the litigation. If securities analysts or investors perceive any of these results to be negative, our stock price could decline.

We may be unable to hire, retain or motivate key personnel, upon whom the success of our business will depend.

We are highly dependent upon certain members of our management and scientific staff, particularly Ron Zwanziger, David Scott and Jerry McAleer. We believe that our future success will depend in large part upon our ability to attract and retain highly skilled scientific, managerial and marketing personnel. We face significant competition for such personnel from other companies, research and academic institutions, government entities and other organizations. We may fail to retain our key employees. Further, we may fail to attract, assimilate, retain or train other needed qualified employees in the future. We do not have employment agreements with all of our key employees. The loss of any of our key employees, including our scientists, may impact or disrupt our sales and marketing activities, our research and development efforts, our capital-raising efforts or our administrative functions.

We may be liable for contamination or other harm caused by hazardous materials that we use.

Our research and development processes involve the use of hazardous materials. We are subject to federal, state and local regulation governing the use, manufacture, handling, storage and disposal of hazardous materials. We cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any contamination or injury. We may also incur expenses relating to compliance with environmental laws. Such expenses or liability could have a significant negative impact on our financial condition.

Our operating results may fluctuate due to various factors and as a result period-to-period comparisons of our results of operations will not necessarily be meaningful.

Factors relating to our business make our future operating results uncertain and may cause them to fluctuate from period to period. Such factors include:

- the timing of new product announcements and introductions by us and our competitors;
- market acceptance of new or enhanced versions of our products;
- changes in manufacturing costs or other expenses;
- competitive pricing pressures;
- the gain or loss of significant distribution outlets or customers;
- the availability and extent of reimbursement for our products;
- increased research and development expenses;

the timing of any future acquisitions;

general economic conditions; or

general stock market conditions, other economic or external factors.

The holders of our Series A Preferred Stock are entitled to receive liquidation payments in preference to the holders of our common stock.

As of March 31, 2002, there were 2,360,246 shares of Series A Preferred Stock outstanding. Pursuant to the terms of the certificate of designation creating the Series A Preferred Stock, upon a liquidation or a deemed liquidation of our company, the holders of the shares of our Series A Preferred Stock are entitled to receive a liquidation payment prior to the payment of any amount with respect to the shares of our common stock. The amount of this preferential liquidation payment is $30 per share of Series A Preferred Stock (or $40.50 per share in certain circumstances), plus the amount of any dividends that have accrued on those shares, subject to adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization affecting our Series A Preferred Stock. Dividends accrue on the shares of our Series A Preferred Stock at the rate of up to $2.10 per share per annum based on the percentage of trading days on which the closing market price of our common stock is less than $15.00. As a result of these terms, the holders of our common stock may be disproportionately affected by any reduction in the value of our assets or fluctuations in the market price of our common stock.

The ability of our stockholders to control our policies and effect a change of control of our company is limited, which may not be in your best interests.

There are provisions in our certificate of incorporation and by-laws which may discourage a third party from making a proposal to acquire us, even if some of our stockholders might consider the proposal to be in their best interests. These provisions include the following:

our certificate of incorporation provides for three classes of directors with the term of office of one class expiring each year, commonly referred to as a staggered board. By preventing stockholders from voting on the election of more than one class of directors at any annual meeting of stockholders, this provision may have the effect of keeping the current members of our board of directors in control for a longer period of time than stockholders may desire; and

our certificate of incorporation authorizes our board of directors to issue shares of preferred stock without stockholder approval and to establish the preferences and rights of any preferred

stock issued, which would allow the board to issue one or more classes or series of preferred stock that could discourage or delay a tender offer or change in control.

Additionally, we are subject to Section 203 of the Delaware General Corporation Law, which, in general, imposes restrictions upon acquirors of 15% or more of our stock. Finally, the board of directors may in the future adopt a shareholder rights plan, which could delay, deter or prevent a change of control.

Because we do not intend to pay dividends, you will benefit from an investment in our common stock only if it appreciates in value.

We currently intend to retain our future earnings, if any, to finance the expansion of our business and do not expect to pay any cash dividends in the foreseeable future. As a result, the success of your investment in our common stock will depend entirely upon any future appreciation. There is no guarantee that our common stock will appreciate in value after the offering or even maintain the price at which you purchased your shares.

SPECIAL STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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. You can identify these statements by forward-looking words such as "may," "could," "should," "would," "intend," "will," "expect," "anticipate," "believe," "estimate," "continue" or similar words. You should read statements that contain these words carefully because they discuss our future expectations, contain projections of our future results of operations or of our financial condition or state other "forward-looking" information. There may be events in the future that we are not able to predict accurately or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. We caution investors that all forward-looking statements involve risks and uncertainties, and actual results may differ materially from those we discuss in this quarterly report on Form 10-Q. These differences may be the result of various factors, including those factors described in the "Risk Factors" section in this quarterly report and other risk factors identified from time to time in our periodic filings with the Securities and Exchange Commission. Some important additional factors that could cause our actual results to differ materially from those projected in any such forward-looking statements are as follows:

economic factors, including inflation and fluctuations in interest rates and foreign currency exchange rates, and the potential effect of such fluctuations on revenues, expenses and resulting margins;

competitive factors, including technological advances achieved and patents attained by competitors and generic competition;

domestic and foreign healthcare changes resulting in pricing pressures, including the continued consolidation among healthcare providers, trends toward managed care and healthcare cost containment and government laws and regulations relating to sales and promotion, reimbursement and pricing generally;

government laws and regulations affecting domestic and foreign operations, including those relating to trade, monetary and fiscal policies, taxes, price controls, regulatory approval of new products and licensing;

manufacturing interruptions, delays or capacity constraints or lack of availability of alternative sources for components for our products;

difficulties inherent in product development, including the potential inability to successfully continue technological innovation, complete clinical trials, obtain regulatory approvals in the United States and abroad, gain and maintain market approval of products and the possibility of encountering infringement claims by competitors with respect to patent or other intellectual property rights which can preclude or delay commercialization of a product;

significant litigation adverse to us including product liability claims, patent infringement claims and antitrust claims;

product efficacy or safety concerns resulting in product recalls or declining sales;

the impact of business combinations, including acquisitions and divestitures, and organizational restructuring consistent with evolving business strategies;

our ability to satisfy the financial covenants and other conditions contained in our credit facilities;

our ability to obtain required financing on terms that are acceptable to us; and

the issuance of new or revised accounting standards by the American Institute of Certified Public Accountants, the Financial Accounting Standards Board or the Securities and Exchange Commission.

The foregoing list sets forth many, but not all, of the factors that could impact upon our ability to achieve results described in any forward-looking statements. Readers should not place undue reliance on our forward-looking statements. Before you invest in our common stock, you should be aware that the occurrence of the events described above and elsewhere in this quarterly report on Form 10-Q could harm our business, prospects, operating results and financial condition. We do not undertake any obligation to update any forward-looking statements as a result of future events or developments.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISKS

The following discussion about our market risk disclosures involves forward-looking statements. Actual results could differ materially from those discussed in the forward-looking statements. We are exposed to market risk related to changes in interest rates and foreign currency exchange rates. We do not use derivative financial instruments for speculative or trading purposes.

Interest Rate Risk

We are exposed to market risk from changes in interest rates primarily through our investing and financing activities. In addition, our ability to finance future acquisition transactions or fund working capital requirements may be impacted if we are not able to obtain appropriate financing at acceptable rates.

Our investing strategy, to manage interest rate exposure, is to invest in short-term, highly liquid investments. Our investment policy also requires investment in approved instruments with an initial maximum allowable maturity of 18 months and an average maturity of our portfolio that should not exceed 6 months, with at least $500,000 cash available at all times. Currently, our short-term investments are in money market funds with original maturities of 90 days or less. At March 31, 2002, our short-term investments approximated market value.

In December 2001, we entered into a series of credit agreements (the "RBS Credit Agreements") with The Royal Bank of Scotland plc and related entities for credit facilities in the aggregate amount of $70 million. These RBS Credit Agreements consisted of term loans aggregating $62.5 million, of which $10 million were denominated in Japanese Yen, and a $7.5 million multicurrency revolving line of credit. To date, we have not utilized the revolving line of credit. The aggregate outstanding loan balance under the RBS Credit Agreements as of March 31, 2002 was $52.3 million, including capitalized interest of approximately $109,000 but net of a reduction of approximately $334,000 resulting from a change in the United States Dollar-to-Japanese Yen exchange rate. The term loans and revolving line of credit allow us to borrow at the London Interbank Offered Rate ("LIBOR") plus a spread from 1.5% to 3.5% (and an additional 2% in case of default), depending on the type of loan (senior or junior) and the interest period. On the loans in which the spread may vary, the spread depends on the ratio of our total debt to earnings before interest expense, taxes, depreciation and amortization ("EBITDA"). In February 2002, we entered into an interest rate swap agreement with the bank, as required by the RBS Credit Agreements, which will protect both our company and the bank from interest rate fluctuations. Under the interest rate swap agreement, the LIBOR rate is set at a minimum of 3.36% and a maximum of 5% and applies to $34.8 to $41.7 million of the term loans denominated in United States Dollars, depending upon the interest period. This interest rate swap agreement is effective for the period from February 25, 2002 to December 31, 2004. Had there not been an interest rate swap agreement in place as of March 31, 2002, the LIBOR applicable to the term loans denominated in United States Dollars would have been 1.9%. The LIBOR applicable to the term loan denominated in Japanese Yen was 0.10% at March 31, 2002. If the LIBOR rate increases one

percentage point, as compared to the rate at March 31, 2002, taking into consideration the terms of the interest rate swap agreement, we estimate an increase in our interest expense of approximately $103,000 over the next twelve months. If the LIBOR rate increases two percentage points, as compared to the rate at March 31, 2002, taking into consideration the terms of the interest rate swap agreement, we estimate an increase in our interest expense of approximately $544,000 over the next twelve months.

Our recently acquired subsidiary, IVC, has a credit agreement with Congress Financial Corporation ("Congress"), a subsidiary of First Union Corporation. Under the credit agreement with Congress, IVC can borrow up to $15.0 million under a revolving credit commitment and $4.2 million under a term loan commitment, subject to borrowing base limitations, as defined in the agreement. The loans with Congress mature on October 16, 2003. As of March 31, 2002, total borrowings outstanding under the credit agreement with Congress were $6.9 million. Borrowings under the revolving credit commitment and the term loan bear interest at either 1.5% above the bank's prime rate or, at IVC's option, at 3.75% above the Adjusted Eurodollar Rate used by the bank. As of March 31, 2002, the interest rate on $5.5 million of the outstanding borrowings was at the Adjusted Eurodollar Rate of 2% plus the spread of 3.75% and the interest rate on the remaining $1.4 million of the

outstanding borrowings was at the prime rate of 4.75% plus the spread of 1.5%. If both the Adjusted Eurodollar Rate and the prime rate increase one percentage point, as compared to the respective rates at March 31, 2002, we estimate an increase in IVC's interest expense of approximately $60,000 over the next twelve months. If both the Adjusted Eurodollar Rate and the prime rate increase two percentage points, as compared to the respective rates at March 31, 2002, we estimate an increase in IVC's interest expense of approximately $120,000 over the next twelve months.

Foreign Currency Risk

We face exposure to movements in foreign currency exchange rates. During the three months ended March 31, 2002, the net impact of foreign currency changes was a gain of $188,000. We expect this exposure to increase because of our expansion into markets outside of the United States as a result of our recent acquisitions of the Unipath business and IVC. Historically, we have not used derivative financial instruments or other financial instruments to hedge economic exposures or for trading. However, because significant amounts of the revenue and expenses of the Unipath business are denominated in foreign currencies, starting in early 2002 we began utilizing foreign exchange forward contracts to minimize exposure to the risk that the eventual net cash inflows and outflows resulting from the sale of products to foreign customers and purchases from foreign suppliers will be adversely affected by changes in exchange rates. Our goal is to utilize foreign exchange forward contracts for recognized receivables and payables and firmly committed cash inflows and outflows. The use of these derivative financial instruments allows us to reduce our overall exposure to exchange rate movements, since the gains and losses on these contracts are expected to substantially offset losses and gains on the assets, liabilities and transactions to which these contracts relate. Cash inflows and outflows denominated in the same foreign currency are netted on a legal entity basis and the corresponding net cash flow exposure is appropriately hedged. As of March 31, 2002, we did not have outstanding foreign exchange forward contracts.

Additionally, as described above, in December 2001 we entered into a series of credit agreements with The Royal Bank of Scotland plc and related entities pursuant to which we borrowed $10.0 million denominated in Japanese Yen (or 1,283 million Japanese Yen). As of March 31, 2002, the outstanding balance of this loan was $8.1 million, net of a reduction of approximately $334,000 resulting from a change in the dollar-to-yen exchange rate. We have not entered into a foreign exchange forward contract to hedge this loan; however, if we do not expect to collect sufficient payments in yen from our royalty contracts recently acquired as part of the Unipath business, we may do so in the future. As of March 31, 2002, the dollar-to-yen exchange rate was approximately 132.77. If the dollar-to-yen exchange rate decreased by ten percent, as compared to the rate at March 31, 2002, we estimate that the

outstanding principal amount owed by us under this loan would have been higher by approximately $900,000 on that date. If the dollar-to-yen exchange rate decreased by twenty percent, as compared to the rate at March 31, 2002, we estimate that the outstanding amount owed by us under this loan would have been higher by approximately $2.0 million on that date. If, on the maturity dates over the next twelve months, the dollar-to-yen exchange rate was lower by ten percent, as compared to the rate at March 31, 2002, we would have to pay approximately $118,000 more in principal repayments during that period. If, on the maturity dates over the next twelve months, the dollar-to-yen exchange rate was lower by twenty percent, as compared to the rate at March 31, 2002, we would have to pay approximately $265,000 more in principal repayments during that period.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

Abbott Laboratories v. Selfcare, Inc. and Princeton BioMeditech Corporation

In April 1998, Abbott Laboratories ("Abbott") commenced a lawsuit against Inverness Medical Technology, Inc. ("IMT"), our former parent and formerly known as Selfcare, Inc., and Princeton BioMeditech Corporation ("PBM"), which manufactured certain products for IMT, in an action filed in the United States District Court for the District of Massachusetts ("District Court"), asserting patent infringement arising from IMT's and PBM's manufacture, use and sale of products that Abbott claims are covered by one or more of the claims of U.S. Patent Nos. 5,073,484 and 5,654,162 (the "Pregnancy Test Patents"), to which Abbott asserts that it is the exclusive licensee. Abbott claims that certain of IMT's products relating to pregnancy detection and ovulation prediction (now our products to the extent they are still sold) infringe the Pregnancy Test Patents. Abbott is seeking an order finding that IMT and PBM infringe the Pregnancy Test Patents, an order permanently enjoining IMT and PBM from infringing the Pregnancy Test Patents, compensatory damages to be determined at trial, treble damages, costs, prejudgment and post-judgment interest on Abbott's compensatory damages, attorneys' fees, and a recall of all of existing products found to

infringe the Pregnancy Test Patents. On August 5, 1998, the court denied Abbott's motion for a preliminary injunction. On March 31, 1999, the District Court granted a motion by IMT, PBM and PBM-Selfcare LLC (the "LLC"), a joint venture between PBM and IMT, filed to amend IMT's counterclaim against Abbott, asserting that Abbott is infringing U.S. Patent Nos. 5,559,041 (the "041 patent") and 5,728,587 (the "587 patent"), which are owned by the LLC, and seeking a declaration that Abbott infringes the patents and that IMT is entitled to permanent injunctive relief, money damages and attorneys' fees. On November 5, 1998, Abbott filed suit in the United States District Court for the Northern District of Illinois seeking a declaratory judgment of non-infringement, unenforceability and invalidity of the 041 patent and the 587 patent. The Illinois court granted IMT's motion to transfer the aforementioned Illinois action to Massachusetts. IMT and its co-defendant moved for summary judgment on its defense that the Abbott patents are invalid, and on September 29, 2000, the court granted partial summary judgment, holding that certain key claims in Abbott's patents are invalid as a matter of law. The court refused to grant summary judgment on Abbott's claims of infringement or IMT's remaining claims of invalidity. On December 17, 2001, the court denied a motion by Abbott seeking reconsideration of the court's partial summary judgment in favor of IMT and PBM. Abbott renewed this motion on February 15, 2002. The court has not ruled on this motion. No trial date has been set at this time. In connection with our split-off from IMT, we assumed all obligations and liabilities of IMT arising out of this matter. We believe that we have strong defenses against Abbott's claims and we will continue to defend the case vigorously; however, a final ruling against IMT or us could have a material adverse impact on our sales, operations or financial performance.

Becton, Dickinson and Company v. Inverness Medical Technology, Inc.

On January 3, 2000, Becton, Dickinson and Company ("Becton Dickinson") filed suit against IMT in the U.S. District Court for the District of Delaware (Case No: 00-001) alleging that certain pregnancy and ovulation products sold by IMT (and now by us) infringe U.S. Patent Nos. 4,703,017 and 5,591,645. IMT was served with Becton Dickinson's complaint in April 2000 and filed its answer on May 30, 2000, and subsequently added counterclaims alleging violations of state and federal antitrust laws. Becton Dickinson has since lost its rights to U.S. Patent No. 5,591,645 and is no longer asserting claims for infringement of that patent. In August 2001, IMT moved for summary judgment of non-infringement, but that motion was denied. IMT subsequently filed a second motion for summary judgment of non-infringement, which is still pending before the court. In connection with our split-off from IMT, we assumed all obligations and liabilities of IMT arising out of this matter and we have assumed its defense. We believe that we have strong defenses and we intend to defend this litigation vigorously.

Intervention, Inc v. Selfcare, Inc. and Companion Cases

In May 1999, Intervention, Inc., a California corporation, filed separate suits, which were subsequently consolidated, in California Contra Costa County Superior Court against IMT (formerly known as Selfcare, Inc.), four of its private label customers (now our customers) and its major competitors (now our competitors) and their private label customers alleging that, under Section 17200 of the California Business and Professions Code, the defendants' labeling on their home pregnancy tests is misleading as to the level of accuracy under certain conditions. The plaintiff seeks restitution of profits on behalf of the general public, injunctive relief and attorneys' fees. Conopco, Inc. ("Conopco"), predecessor to one of our subsidiaries, Unipath Diagostics, Inc. ("Unipath Diagnostics"), was also a defendant in this litigation. In connection with our split-off from IMT and our acquisition of the Unipath business from Unilever, we assumed the defense of IMT and Unipath Diagnostics and agreed to assume all obligations and liabilities of IMT and Unilever arising out of this matter. More recently the case has been split such that Unipath Diagnostics is a defendant in one case and we and our private label customers are defendants in another case. The case in which we and our private label customers are parties is scheduled for trial in June 2002. No trial date has been established for the case in which Unipath Diagnostics is a party. We are defending our private label customers under agreement. We do not believe that an adverse ruling against our company, our private label customers or Unipath Diagnostics would have a material adverse impact on our sales, operations or financial performance.

Persona Litigation

In April 2001, 69 consumers brought an action in London claiming defects in Unipath's Persona contraceptive device, negligence and breach of contract, all allegedly leading to unwanted pregnancies by the claimants at or prior to 1998. The case is expected to be ready for trial to a judge in the latter half of 2003. We believe that there are substantial defenses to the claims and we intend to vigorously defend this litigation. Formal documentary and other discovery permitted under the law in the United Kingdom has not yet commenced, but is anticipated to be conducted during the second half of 2002 and into 2003. The case is insured, in the aggregate, by Unilever's product liability insurance up to 50 million British Pounds Sterling or more, depending on when the events giving rise to the consumers' suit occurred. As a result, we do not believe that an adverse ruling against us would have a material adverse impact on our sales, operations or financial performance.

Other Pending and Potential Litigation

Because of the nature of our business, we may be subject at any particular time to consumer product claims or various other lawsuits arising in the ordinary course of our business, including employment matters, and expect that this will continue to be the case in the future. These

lawsuits generally seek damages, sometimes in substantial amounts, for personal injuries or other commercial or employment claims. We believe that any adverse ruling in such lawsuits would not have a material adverse effect on our sales, operations or financial performance. In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties, which can be expensive and results in counterclaims challenging the validity of our patents and other rights. We are currently a plaintiff in a number of cases filed around the world against competitors who we believe to be selling products that infringe our propriety rights. In particular, on March 7, 2002, we filed suit against Pfizer, Inc. ("Pfizer") in the United States District Court for the District of New Jersey alleging that Pfizer's e.p.t ® brand pregnancy tests infringe Unipath's United States Patent Number 6,352,862 and seeking injunctive relief against further infringement as well as damages. This case compliments two existing infringement cases that we have pending against Pfizer based on other Unipath patents. The defendants have filed counterclaims alleging, among other things, invalidity of the relevant patents.

ITEM 2. CHANGES IN SECURITIES AND USE OF PROCEEDS

Set forth below is information regarding unregistered securities issued by our company during the three months ended March 31, 2002. No underwriters or underwriting discounts or commissions were involved. There was no public offering in the transaction described below and we believe that this transaction was exempt from the registration requirements of the Securities Act of 1933, as amended, by reason of Section 4(2) thereof, based on the private nature of the transactions and the financial sophistication of the purchasers, all of whom had access to complete information concerning our company and acquired the securities for investment and not with a view to the distribution thereof.

On March 6, 2002, we sold an aggregate of 531,913 shares of Series A Preferred Stock to private investors at a purchase price of $39.01 per share for an aggregate consideration of approximately $20.75 million. The Series A Preferred Stock is currently convertible into common stock at a 2-for-1 ratio, subject to adjustment. Accordingly, these shares of Series A Preferred Stock are currently convertible into 1,063,826 shares of common stock. For additional information regarding the identity of the purchasers of the Series A Preferred Stock, see the signature pages to the Stock Purchase Agreement included as Exhibit 99.2 to our current report on Form 8-K dated March 14, 2002, as amended, which information is incorporated herein by reference.

On March 7, 2002, we issued 333,334 shares of common stock upon conversion of 166,667 shares of Series A Preferred Stock pursuant to an exemption afforded by Section 3(a)(9) of the Securities Act of 1933, as amended.

ITEM 6. EXHIBITS AND REPORTS ON FORM 8-K

a. Exhibits:

Exhibit No.	Description
*10.1	Supply of Goods Agreement, dated December 19, 1994, between AFC Worldwide and Unipath Limited
*10.2	Amendment to Supply of Goods Agreement, dated March 14, 2002, between Schleicher & Schuell GmbH and Unipath Limited.
*10.3	Amendment No. 1 to Inverness Medical Innovations, Inc. Executive Bonus Plan

*

Filed as an exhibit to the quarterly report on Form 10-Q for the quarter ended March 31, 2002 on May 13, 2002.

b. Reports on Form 8-K:

On January 4, 2002, we filed a Current Report on Form 8-K (Items 2 and 7) dated December 20, 2001 in connection with our acquisition of the Unipath business.

On March 5, 2002, we filed a Current Report on Form 8-K/A (Item 7) dated December 20, 2001 in connection with our acquisition of the Unipath business. The Current Report on Form 8-K/A included the following financial statements:

Audited combined financial statements of the Unipath Division of Unilever Plc as of November 30, 2001 and December 31, 2000 and for the eleven months ended November 30, 2001 and the years ended December 31, 2000 and 1999; and

Unaudited pro forma financial information of our company as of and for the eleven months ended November 30, 2001 giving pro forma effect to our acquisition of the Unipath business.

On March 14, 2002, we filed a Current Report on Form 8-K (Items 5 and 7) dated March 6, 2002 in connection with our sale of Series A Preferred Stock to private investors.

On March 29, 2002, we filed a Current Report on Form 8-K (Items 2 and 7) dated March 19, 2002 in connection with our acquisition of IVC Industries, Inc.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

INVERNESS MEDICAL INNOVATIONS, INC.

Date: August 28, 2002 By: /s/ DUANE L. JAMES

Duane L. James
Vice President of Finance and an authorized officer

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