INVERNESS MEDICAL INNOVATIONS INC
Form 10-K/A
April 22, 2004

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K/A

(Amendment No. 1)

(Mark One)

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2003

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 000-16789

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)	(Zip Code)

(781) 647-3900

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, $0.001 per share par value	American Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ý No o

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. Yes o No ý

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2). Yes ý No o

The aggregate market value of the voting common stock held by non-affiliates of the registrant based on the closing price of the registrant's stock on the American Stock Exchange on June 30, 2003 (the last business day of the registrant's most recently completed second fiscal quarter) was $249,917,109. For this computation, the registrant has excluded the market value of all shares of common stock reported as beneficially owned by executive officers and directors of the registrant; such exclusion shall not be deemed to constitute an admission that any such person is an affiliate of the registrant.

As of March 12, 2004, the registrant had 20,094,405 shares of common stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission on or prior to April 29, 2004 are incorporated by reference into Part III of this Form 10-K/A.

EXPLANATORY NOTE

The Division of Enforcement of the Securities and Exchange Commission (the "SEC") recently concluded its informal investigation arising out of the resignation in April 2003 of our former independent auditor, Ernst & Young LLP, without taking any action against us. In concluding its informal investigation, the status of which as of March 15, 2004 is discussed on pages 18 and 58 of this Annual Report on Form 10-K/A, the SEC informed us that it disagreed with the accounting that we followed in recognizing a $2.6 million realized foreign currency gain arising from the settlement of a long-term intercompany loan in the fourth quarter of 2002, and indicated its belief that the change in the value of the settled balance due to currency movements should have been reflected on the balance sheet as a component of accumulated other comprehensive income. We had sought the advice of our former auditor and accounted for the transaction in accordance with this advice. We recognize, however, the important role that the SEC plays in assisting public companies and their auditors in interpreting accounting principles generally accepted in the United States of America and, in accepting the SEC's advice, we agreed to file this Amendment No. 1 (the "Amended Report") to our Annual Report on Form 10-K for the fiscal year ended December 31, 2003 (the "Original Report") in order to restate the 2002 financial statements included in the Original Report.

The SEC also suggested that, while we were making the restatement discussed above, we consider reallocating certain amounts previously recorded as adjustments in the quarters in which they were identified to the earlier quarters to which they related. We have accepted the SEC's advice and incorporated these changes into our 2002 and 2003 financial results included in the Amended Report and, in particular, into our quarterly results for 2002 and the first quarter of 2003 included in the Supplementary Quarterly Financial Information provided in Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations."

For the reasons discussed above, we are filing this Amended Report in order to amend Item 6 "Selected Financial Data," Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations," Item 8 "Financial Statements and Supplementary Data" and Item 15 "Exhibits, Financial Statement Schedules and Reports on Form 8-K" of the Original Report solely to the extent necessary to reflect the adjustments discussed above. The remaining Items of our Original Report are not amended hereby and are repeated herein only for the reader's convenience.

In order to preserve the nature and character of the disclosures set forth in the Original Report, except as expressly noted above, this report speaks as of the date of the filing of the Original Report, March 15, 2004, and we have not updated the disclosures in this report to speak as of a later date. All information contained in this Amended Report is subject to updating and supplementing as provided in our reports filed with the SEC subsequent to the date of the Original Report.

PART I

This annual report on Form 10-K 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 report. There are a number of important factors that could cause our actual results to differ materially from those projected by such forward-looking statements. These factors include, but are not limited to, the risk factors

detailed in this report and other risk factors identified from time to time in our periodic filings with the Securities and Exchange Commission. You 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 50 and 65, respectively, in this report 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 annual report on Form 10-K to "we," "us," "our," or "our company" refer to Inverness Medical Innovations, Inc. and its subsidiaries, and their respective predecessor entities for the applicable periods, considered as a single enterprise.

We have registered, applied to register or are using the following trademarks: Clearblue®, Clearblue Easy®, Fact plus®, Accu-Clear™, ClearPlan®, ClearPlan Easy®, Persona®, Ferro-Sequels™, Stresstabs®, Protegra®, Posture®, SoyCare™, ALLBEE®, Z-BEC®, Clearview®, Wampole®, SureStep™, Osteomark®, TestPack™, Signify®, SmartCare®, Isolator™, InstaCheck®, InstaCup®, InstaStick®, CheckCup®, ImmunoComb™, DoubleCheck™ and ImmunoGold™.

The following are trademarks of parties other than us: Abbott TestPack®, Abbott TestPack plus®, e.p.t®, Labotech®, Personal LAB™, Athena Multi-Lyte™, Micro Trak™, Triomega®, Pronova Biocare® and Walgreens®.

ITEM 1. BUSINESS

OVERVIEW

We are a leading global developer, manufacturer and marketer of in vitro diagnostic products for the over-the-counter pregnancy and fertility/ovulation test market and the professional rapid diagnostic test market. Our business is organized into two reportable segments, consumer products and professional diagnostics. Through our consumer products segment, we hold a leadership position in the worldwide over-the-counter pregnancy and fertility/ovulation test market. We sell our pregnancy and fertility/ovulation test products in the premium branded sector, the value branded sector and the private label sector. In addition, we manufacture and market a variety of vitamins and nutritional supplements under our brands and those of private label retailers primarily in the U.S. consumer market. Through our professional diagnostics segment, we develop, manufacture and market an extensive array of innovative rapid diagnostic test products and other in vitro diagnostic tests to medical professionals and laboratories for detection of infectious diseases, drugs of abuse and pregnancy. Today, we are a leader in the worldwide professional rapid diagnostic test market. We have grown our consumer products and professional diagnostics segments by leveraging our strong intellectual property portfolio and making selected strategic acquisitions. Our consumer and professional diagnostic products are sold in approximately 90 countries through our direct sales force and an extensive network of independent global distributors.

Our consumer products segment primarily targets the women's health market through home pregnancy detection tests and home fertility/ovulation prediction tests. In this market, we offer premium branded products, including Clearblue, value branded products, including Accu-Clear, and private label products. Our Clearblue branded pregnancy test was the first one-step pregnancy test and currently holds a leadership position globally. We also recently launched our new digital pregnancy test, Clearblue Easy Digital, which was the first consumer pregnancy test to display test results in words, and our Clearblue Easy Fertility Monitor remains the only hormone-based reusable monitoring device available for home use to assist women attempting to conceive. Additionally, we have entered into two separate supply arrangements with Pfizer pursuant to which we agreed to supply Pfizer with a digital version of its e.p.t pregnancy tests on a non-exclusive basis beginning in December 2003 and the non-

digital version of its premium branded e.p.t pregnancy tests beginning in June 2004 and continuing for five years. We sell our premium and value branded products over-the-counter through drugstores, groceries and mass merchandisers, and we sell our private label products to major retailers such as Walgreens, CVS, RiteAid and Boots. As a part of our consumer products segment, we also market a wide variety of vitamins and nutritional supplements through retail drug stores, mass merchandisers, groceries and warehouse clubs primarily within the United States.

Our professional diagnostics segment consists of diagnostic test products designed to assist medical professionals in both preventative and interventional medicine. We offer our customers an extensive array of rapid diagnostic test products, which address the need for quick, accurate results at the point-of-care. We also offer products in a variety of other platforms, including enzyme linked immunosorbent assay (ELISA, tests), the AtheNA Multi-Lyte ANA Test System, indirect fluorescent antibody and microbiology assay tests and serology diagnostic products. Our products test for infectious diseases, including tests for Epstein-Barr virus, strep throat, herpes simplex virus, measles and mumps; pregnancy; autoimmune disease; bone resorption, to assist in managing osteoporosis; and drugs of abuse. Through our direct sales force and distributor relationships, we have access to the major customers in the professional diagnostic test market, including hospitals, reference labs, physicians' offices and other point-of-care settings.

Inverness Medical Innovations, Inc. is a Delaware corporation. Our principal executive offices are located at 51 Sawyer Road, Suite 200, Waltham, Massachusetts 02453 and our telephone number is (781) 647-3900. Our common stock is listed on the American Stock Exchange under the symbol "IMA."

Our web site is www.invmed.com and we make available through this site, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports, filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after such reports are electronically filed with, or furnished to, the SEC. These reports may be accessed through our website's company information page.

RECENT DEVELOPMENTS

Private Placement of 8 3/4% Senior Subordinated Notes

On February 10, 2004, we completed the sale of $150 million of 8 3/4% senior subordinated notes due 2012 in a private placement to qualified institutional buyers. Interest on the senior subordinated notes is payable semi-annually in arrears on each February 15 and August 15, commencing on August 15, 2004. The senior subordinated notes are unsecured and are subordinated to all of our existing and future senior debt, including our guarantee of all borrowings under our senior credit facility. The senior subordinated notes are guaranteed by all of our domestic subsidiaries that are guarantors or borrowers under our senior credit facility. The indenture governing the senior subordinated notes contains covenants that restrict our ability to, among other things, incur additional indebtedness, pay dividends, redeem stock, make investments, sell assets, incur liens and consolidate, merge or sell all or substantially all of our assets. We have agreed to file a registration statement that will enable the holders of the senior subordinated notes to exchange the privately placed notes for publicly registered notes with substantially identical terms.

We used $134.5 million of the proceeds to repay all of our outstanding term indebtedness, as well as to fully pay down the revolving credit facilities under our senior credit facility, and to fully repay our outstanding 9% subordinated promissory notes, including prepayment penalties. The net proceeds of approximately $11.4 million will be used for general corporate purposes, as well as to pay additional expenses related to the sale of the senior subordinated notes. We also retained access to up to $50 million in available credit under the revolving credit facilities that were repaid.

BUSINESS SEGMENTS AND GEOGRAPHIC AREA

Our major reportable segments are consumer products and professional diagnostics. Our consumer products are further divisible into consumer diagnostics, which includes our home pregnancy detection and fertility/ovulation prediction tests, and vitamins and nutritional supplements. We further categorize our sales by major geographic areas of the world. Below are discussions of each of our reportable segments. Financial information about our reportable segments is provided in Note 15 of the "Notes to Consolidated Financial Statements," which are included elsewhere in this report.

Industry

Consumer Products

Consumer Diagnostics. Our current consumer diagnostic products target the worldwide over-the-counter pregnancy and fertility/ovulation test market. There are numerous pregnancy self-tests on the market, which are typically urine-based tests and provide results in less than five minutes. These tests represent a safe, easy and effective method for women to manage their reproductive health at home. Fertility/ovulation prediction tests inform women of the best time to conceive a baby by detecting the surge of the luteinizing hormone, which precedes ovulation. Fertility/ovulation prediction tests are generally easy to use and urine-based fertility/ovulation prediction tests have become widely accepted for home use by professional fertility care providers and the general public. Urine-based fertility/ovulation tests consist of disposable stick tests, which are similar to pregnancy tests, and fertility monitoring devices, such as our Clearblue Easy Fertility Monitor, which is the only commercially available reusable monitoring device which measures estrogen levels as well as the luteinizing hormone. There are also saliva-based fertility/ovulation tests on the market which are lower cost alternatives to urine-based tests, but generally are not as easy to interpret and do not provide notification of ovulation as early as urine-based tests can.

Vitamins and Nutritional Supplements. According to Nutrition Business Journal estimates, total mass merchandise retail sales of vitamins and nutritional supplements in the United States during 2002 were approximately $6 billion. Most growth in the industry is attributed to new products that generate attention in the marketplace. Well-established market segments, where competition is greater and media commentary less frequent, are generally stable. Slow overall growth in the industry has resulted in retailers reducing shelf space for nutritional supplements and has forced many under-performing items out of distribution, including several broad product lines. Sales growth of private label products has generally outpaced the overall industry growth, as retailers continue to add to the number of private label nutritional products on their shelves.

Professional Diagnostics

The professional diagnostics market consists of products designed to assist medical professionals in both preventative and interventional medicine. These products provide for qualitative or quantitative analysis of a patient's body fluids or tissue for evidence of a specific medical condition or disease state or to measure response to therapy. Today, we are a leader in the worldwide professional rapid diagnostic test market, which we define to include only the professional point-of-care pregnancy, infectious disease and drugs of abuse test markets. This market consists primarily of small and medium-sized, non-centralized laboratories and testing locations such as physician office laboratories, small blood banks, specialist mobile clinics and some rapid-response laboratories in larger medical centers. We distinguish the professional point-of-care rapid diagnostic test market from clinical diagnostic markets that consist of large, centralized laboratories that offer a wide range of highly-automated laboratory services in hospital or related settings.

We believe that the demand for infectious disease diagnostic products is growing faster than demand in many other segments of the non-laboratory, or point-of-care, immunoassay market due to

the increasing incidence of certain diseases or groups of diseases, including lyme disease, viral hepatitis, acquired immunodeficiency syndrome, respiratory syncytial virus (RSV) and tuberculosis, as well as HIV, chlamydia and other sexually transmitted diseases. In general, we believe that the ability to deliver faster, accurate results at reasonable prices drives demand for professional diagnostic products. This means that while there is certainly growing demand for faster, more efficient automated equipment from large hospitals and major reference testing laboratories, there is also growing demand by point-of-care facilities and smaller laboratories for fast, high-quality, inexpensive, self-contained diagnostic kits. As the speed and accuracy of such products improve, we believe that these products will play an increasingly important role in achieving early diagnosis, timely intervention and therapy-monitoring outside of acute medicine environments.

Products

Consumer Products

Consumer Diagnostics. Through our consumer products business, we develop, manufacture and market home pregnancy and fertility/ovulation prediction tests. We offer premium branded products, value branded products and private label products. Our Clearblue home pregnancy and fertility/ovulation prediction tests are global leaders in terms of both sales and technology and our Clearblue Easy Fertility Monitor is the only hormone-based reusable monitoring device available for home use to assist women attempting to conceive. Our Accu-Clear branded pregnancy and fertility/ovulation prediction products are marketed to value-oriented consumers in the United States. We also recently acquired Fact plus, another leading brand pregnancy test from Abbott Laboratories, We are also a major U.S. supplier of private label home pregnancy detection and fertility/ovulation prediction products. We have supply arrangements with Pfizer pursuant to which we agreed to supply Pfizer with a digital version of its e.p.t pregnancy tests on a non-exclusive basis beginning in December 2003 and the non-digital version of its premium branded e.p.t pregnancy tests beginning in June 2004 and continuing for five years. We also sell Persona, a diagnostic monitoring device that provides for a natural method of contraception by allowing the user to monitor her menstrual cycle, in foreign countries, primarily in Germany and the United Kingdom.

Pregnancy Test Products. We market our pregnancy self-test kits in both stick and cassette versions. The stick version has an exposed wick which absorbs urine when placed in the urine stream. The cassette version requires the user to first collect a urine sample in a cup and then use an enclosed dropper to place the urine sample in the test well. Both versions display visual results in approximately one minute or three minutes, depending on the product. Additionally, in the second quarter of 2003, we launched our new digital pregnancy test, Clearblue Easy Digital, which was the first consumer pregnancy test on the market to display test results in words. Instead of interpreting colored lines for a result, the digital display will spell out "Pregnant" or "Not Pregnant." We sell our premium and value branded products over-the-counter through drugstores, groceries and mass merchandisers, and we sell our private label products to major retailers such as Walgreens, CVS, RiteAid and Boots.

Fertility/Ovulation Prediction Products. We market our fertility/ovulation prediction self-test kits in stick and cassette versions, each of which operates in a manner similar to the comparable version of our pregnancy self-test kits. We market our fertility/ovulation prediction test kits under our own brand names and under various store brand labels of retail drugstores, groceries and mass merchandisers. Our fertility/ovulation prediction test kits provide 24 to 48 hours notice of when ovulation is likely to occur. By identifying the days when a woman is most fertile, these products assist couples in planning conception. Clinically accurate results are available in approximately three minutes.

We also market an advanced fertility/ovulation prediction self-test device called the Clearblue Easy Fertility Monitor. The Fertility Monitor not only detects the surge of the luteinizing hormone, or LH, which causes ovulation, but it is also the only fertility/ovulation prediction device that identifies additional days when a woman may conceive by detecting a rise in estrogen levels that precedes the LH surge. The Fertility Monitor is comprised of a hand held monitoring device and disposable urine test sticks. This product is sold primarily in the United States and Canada.

Persona. Persona is a diagnostic monitoring device that provides for a natural method of contraception by allowing the user to monitor her menstrual cycle. Persona is comprised of a hand-held monitoring device and disposable urine test sticks. Persona is sold in Europe, primarily in Germany and the United Kingdom, where it is classified as a contraceptive device. We do not have, and have not applied for, regulatory approval to sell Persona in the United States.

Vitamins and Nutritional Supplements. We market a wide variety of vitamins and nutritional supplements through retail drug stores, mass merchandisers, groceries and warehouse clubs primarily within the United States. Inverness Medical Nutritionals Group, or IMN, is a national supplier of private label vitamin and nutritional products for major drug and food chains and also manufactures bulk vitamins, minerals and nutritional supplements under contract for unaffiliated brand name distributors. IMN also manufactures an assortment of vitamin, mineral and nutritional supplement products for sale under Inverness Medical brand names.

Our Inverness Medical branded nutritional products are high quality products sold at moderate prices through national and regional drug stores, groceries and mass merchandisers. These branded products include Stresstabs, a B-complex vitamin with added antioxidants; Ferro-Sequels, a time-release iron supplement; Protegra, an antioxidant vitamin and mineral supplement; Posture-D, a calcium supplement; SoyCare, a soy supplement for menopause; ALLBEE, a line of B-complex vitamins; and Z-BEC, a zinc supplement with B-complex vitamins and added antioxidants. We also market these branded products under the SmartCare program, which assists consumers in matching their health concerns to the appropriate supplement products that we sell. SmartCare provides a means of linking our various nutritional supplement products, allowing for greater efficiencies in advertising, promotion and merchandising. We have recently entered into agreements to serve as the exclusive U.S. manufacturer and distributor of Triomega, an omega-3 dietary supplement owned by Pronova Biocare. We introduced Triomega, a leading brand in Europe, to the U.S. market in December 2003.

Professional Diagnostic Products

We develop and market a broad range of diagnostic tests that are sold to professional diagnostic users. In the United States, our professional diagnostic products are sold under our Wampole, SureStep, Signify and Clearview labels and we also distribute products on behalf of third parties. Outside of the United States, we market our Clearview, SureStep and TestPack products, as well as several proprietary platforms of products manufactured by our subsidiary Orgenics, Ltd., located in Yavne, Israel. Our professional diagnostic products include:

Rapid Membrane Test Products. We develop and market a wide variety of rapid membrane tests for pregnancy, drugs of abuse, mononucleosis, strep throat, C.difficile, lyme disease, chlamydia, H.pylori and rubella. These products, which include our Clearview, SureStep, Signify and TestPack brands, are qualitative, visually-interpreted rapid diagnostic tests that are used in point-of-care environments where a rapid response is desired or where the volume of testing is too low to warrant high-volume methods. Our DoubleCheck and ImmunoGold platforms are low-cost rapid tests sold outside of the United States and include tests for HIV and hepatitis.

ELISA Products. We offer over 70 enzyme linked immunosorbent assays (ELISA) tests for infectious and sexually transmitted diseases, including tests for Epstein-Barr virus (EBV), TORCH (toxoplasmosis, rubella, cytomegalovirus and herpes simplex virus), H.pylori, lyme disease, syphilis, measles, mumps, varicella zoster virus, or VZV, and Legionella; enteric disease testing for C.difficile, Giardia, Cryptosporidium, E. histolytica and chlamydia; autoimmune disease; bone resorption to assist in managing osteoporosis; and cardiac risk assessment. We also offer a full line of automated instrumentation for processing ELISA assays including the Labotech and PersonalLAB systems. Our ImmunoComb line of products is a manual ELISA testing platform marketed outside the United States as a low cost alternative to more expensive automated ELISA platforms.

AtheNA Multi-Lyte ANA Test System. We recently introduced, and are the exclusive U.S. distributor of, the AtheNA Multi-Lyte ANA Test System, which is capable of simultaneously performing an anti-nuclear antibody, or ANA, screen and reflex testing for nine specific auto-antibodies in a single well. The test system may be used as an aid in the diagnosis of patients with various autoimmune diseases and connective tissue disorders, such as systemic lupus erythematosus, mixed connective tissue disease, Sjogren's Syndrome, Crest syndrome and myositis. The AtheNA Multi-Lyte ANA test provides improved clinical sensitivity and comparable clinical specificity to ELISA in a labor saving, automated user-friendly format.

IFA and Microbiology Assays. We also offer a line of indirect fluorescent antibody, or IFA, assays for over 20 viral, bacterial and autoimmune diseases. Our Isolator Blood Culture system provides rapid isolation and improved recovery of microorganisms in the blood, and our MicroTrak family of products test for sexually transmitted diseases, including Chlamydia EIA, Chlamydia DFA and herpes simplex virus.

Serology Diagnostic Products. We also offer a full line of serology diagnostic products covering a broad range of disease categories, including mononucleosis, rheumatoid arthritis, C-reactive protein, syphilis, rubella and streptococcal infections. Many of our kits are available in multiple formats including rapid membrane, latex, red cell and color-enhanced agglutination. These serology assays provide cost-effective testing alternatives and most offer results in two minutes or less.

Marketing and Sales

Consumer Products

Consumer Diagnostic Products. We market and sell our consumer diagnostic products under our own brand names as well as under store brands. Our customers include retail drug stores, drug wholesalers, groceries and mass merchandisers in North America, Europe and Japan. Our Clearblue brand pregnancy detection and fertility/ovulation prediction tests, which are marketed under the name Clearblue Easy in the United States, is a leading brand both in the United States and globally. Our Clearblue products are marketed as premium products and compete intensively with other premium brand name products. Persona is also marketed as a premium product in Europe. Marketing of premium branded products focuses on brand awareness as well as feature and performance differentiation. We achieve this through television and print advertising. Our Fact plus and Accu-Clear brand products compete primarily based on price and are not heavily advertised. Our consumer diagnostic products are marketed in the United States, the United Kingdom and in Germany using our own sales managers and a network of sales representatives. In other areas of the world, including Japan, Canada, Australia and the rest of Europe, our Clearblue products are sold though distribution contracts with large consumer diagnostics companies. Private label and contract manufacturing arrangements accounted for 19% of our consumer diagnostics business' net product sales for 2003. Our

five largest customers during the fiscal year ended December 31, 2003, based on net product sales, were Walgreen Co., Boots Company, CVS Corporation, Laboratoires Polive and RiteAid.

Vitamins and Nutritional Supplements. We primarily market and sell our vitamins and nutritional supplements in the United States through private label arrangements with retail drug stores, groceries, mass merchandisers and warehouse clubs who sell our products under their store brands. We also sell a variety of branded products, most of which we own but certain of which we distribute for third parties, to the retail drug stores, groceries and mass merchandisers. To a lesser extent we provide contract manufacturing services to third parties. Our two largest customers during 2003, based on net product sales, were Walgreens and Costco. Our rights to the trademarks Stresstabs, Ferro-Sequels, Posture-D, Protegra, ALLBEE and Z-BEC are limited to use in North America, but we are not restricted from marketing the formulations sold under those brand names under other brand names outside of North America.

Professional Diagnostic Products

In the United States, we distribute our professional diagnostic products to hospitals, reference laboratories, physician's offices and other point-of-care settings through our extensive sales and distribution network. For the fiscal year ended December 31, 2003, the five largest customers of our U.S. professional diagnostics business were Cardinal Health, Fisher Scientific, Laboratory Corporation of America, PSS World Medical and Quest Diagnostics.

In Germany, we also sell our Clearview products using our own sales force. Otherwise, we sell our Clearview products outside the United States through third party distributors. We also sell a C.difficile test and a Listeria test product that we manufacture at our Bedford facility to an unaffiliated company who markets the products under its own brands. That arrangement prohibits us from selling these tests directly or to other resellers with the exception that we sell the C.difficile test in the United States. Five countries, the United States, Germany, the United Kingdom, Japan and China, represent a majority of our sales of Clearview products.

We have also entered into a distribution arrangement with Abbott Laboratories in connection with our acquisition of the Abbott rapid diagnostics product lines. Under this arrangement, Abbott has also agreed to serve for two years from September 30, 2003 as our U.S. distributor for the Signify product line, except to physician office laboratories currently served by PSS World Medical, Inc., and, to the extent reintroduced in the United States, the TestPack product line. Outside the United States, Abbott will distribute the TestPack and Signify product lines for us for up to eighteen months from September 30, 2003.

Our Orgenics products are sold through sales offices, the largest of which are in Israel, France and Brazil, which market those products to smaller laboratories, blood banks, physicians' offices and other patient point-of-care sites in approximately 90 countries, principally in Europe, Latin America, Africa and Asia.

Many of our professional diagnostic products are manufactured by third parties and, in some cases, our distribution rights are limited to the United States. Our Orgenics products, one of our Clearview products and our TestPack products, are not approved for sale, and are not sold, in the United States.

Manufacturing

Consumer Products

Consumer Diagnostic Products. We manufacture nearly all of our disposable consumer diagnostic products at our facilities in Bedford, England, Galway, Ireland and San Diego, California. These facilities employ modern production techniques to produce consistent, high-quality components and each is ISO certified and registered with the United States Food and Drug Administration, the FDA.

We use our Bedford facility to manufacture the diagnostic test portion of our new digital pregnancy test, Clearblue Easy Digital, and the digital e.p.t pregnancy test for Pfizer, and we anticipate using this facility to manufacture the non-digital e.p.t pregnancy test for Pfizer in connection with our five-year supply arrangement with Pfizer for this product that begins in June 2004. Our Fact plus pregnancy tests intended for distribution outside of the United States are currently manufactured by Abbott Laboratories under a transitional arrangement entered into in connection with our recent acquisition of the Abbott rapid diagnostics product lines. A significant portion of our products produced and assembled at our Galway plant is subsequently packaged by third parties under contract in the United States. We purchase the electronic portion of our digital pregnancy tests, our Clearblue Easy Fertility Monitor and Persona to our specifications from third party suppliers in Europe and China. Because most components of our consumer diagnostic products are produced to our specifications, some of our suppliers are single source suppliers with few, if any, alternative sources immediately available.

We are currently using the Bedford facility pursuant to an agreement with Unilever entered into in connection with our acquisition of the Unipath business in 2001. For more information regarding our use of the Bedford facility and the risks associated with our arrangement to use this facility see "Certain Factors Affecting Future Results 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 multi-purpose facility that we currently use in Bedford, England."

Vitamins and Nutritional Supplements. We manufacture substantially all of our vitamin and nutritional products at IMN's facilities in Freehold and Irvington, New Jersey. The facility located in Freehold, New Jersey is equipped with large-volume blending, tableting and coating equipment, packaging equipment, including "cartoning," "stretch carding" and "blister carding" equipment, and testing and quality control laboratories. IMN internally manufactures substantially all of its softgel requirements at the Irvington facility. Our Freehold facility manufactures in full compliance with GMP standards recently proposed by the FDA for the dietary supplement industry. Our Irvington facility manufactures to GMP standards applicable to drug makers and is registered with both the United States Drug Enforcement Agency, or the DEA, and the FDA.

Professional Diagnostic Products

Approximately 57% of the professional diagnostic products that we sell, based on net product sales for the fiscal year ended December 31, 2003, were manufactured by third parties. We manufacture the products we acquired through our acquisition of Applied Biotech, Inc., or ABI, as well as certain of the Abbott rapid diagnostics product lines, at our facilities in San Diego, California. Certain of the remaining Abbott rapid diagnostics product lines, namely the TestPack products, will be manufactured by Abbott under a transitional arrangement until we can transition manufacturing of these products to our own facilities. Most of the Signify products acquired from Abbott are currently manufactured by a third party, with the remainder manufactured by ABI. Our Clearview diagnostic products are manufactured at our facility in Bedford, England, which is described above, and our Orgenics products are manufactured in Yavne, Israel. A portion of our Osteomark products are manufactured at our Galway facility and we are in the process of transferring the manufacturing of the remaining products from our facilities in Seattle to a third-party manufacturer. The Bedford, Galway, Yavne and San Diego manufacturing facilities are ISO certified.

Research and Development

A significant portion our budget for research and development currently is allocated to the development of products targeting new markets that are new to us, including products for osteoporosis and cardiovascular disease management. The remainder of our research and development efforts is focused on enhanced features for our lines of consumer and professional diagnostic products. Most of our research and development activities are carried out at our corporate research and development center in Bedford, England, but we also conduct research and development at our facilities in Galway, San Diego, Yavne and Farum, Denmark. We may, from time to time, supplement our internal research and development efforts with third parties' efforts either through co-development or licensing arrangements, or through product or technology acquisitions. In connection with co-development or licensing activities that we may enter into in the future, we may provide financial development assistance to these parties and may also utilize our own research and development resources to design certain portions of such products.

Foreign Operations

Our business relies heavily on our foreign operations. Three of our seven current manufacturing facilities are outside the United States, including our primary consumer diagnostic manufacturing facilities in Bedford, England and Galway, Ireland. Approximately 36% of our net revenues were generated from outside of the United States during 2003. Our Clearblue products, pregnancy tests in particular, have historically been much stronger brands outside the United States, with 75% of our net product sales of Clearblue products coming from outside the United States during 2003. Persona is sold exclusively outside of the United States, and our Orgenics professional diagnostic products have always been sold exclusively outside of the United States. In addition, our newly acquired TestPack product line is sold exclusively outside the United States.

Competition

General

We have existing competitors, as well as a number of potential new competitors, who have greater name recognition, and significantly greater financial, technical and marketing resources than we do. These strengths may allow them to devote greater resources than we can to the development, marketing and sales of products. These competitors may also engage in more extensive research and development, undertake more far-reaching marketing campaigns and adopt more aggressive pricing policies and make more attractive offers to existing and potential employees, customers and clients.

We expect that industry forces will impact us and our competitors. Our competitors will likely strive to improve their product offerings and price competitiveness. We also expect our competitors to develop new strategic relationships with providers, referral sources and payors, which could result in increased competition. The introduction of new and enhanced services, acquisitions and industry consolidation, and the development of strategic relationships by our competitors could cause a decline in sales or loss of market acceptance of our products, intensify price competition or make our products less attractive. We cannot assure you that we will be able to compete successfully against current or future competitors or that competitive pressures will not have a material adverse effect on our business, financial condition and results of operations.

Consumer Products

Consumer Diagnostic Products. Competition in the pregnancy detection and fertility/ovulation prediction market is intense. Our competitors in the United States, and worldwide, are numerous and include, among others, large medical and consumer products companies as well as numerous private label manufacturers. Our competitors for the sale of pregnancy test products worldwide include

Armkel, Pfizer, Acon Laboratories, Omega Pharma, Princeton BioMeditech, Arax and Syntron Bioresearch, although we have recently entered into two separate supply arrangements with Pfizer pursuant to which we agreed to supply Pfizer with a digital version of its e.p.t pregnancy tests on a non-exclusive basis beginning in December 2003 and the non-digital version of its premium branded e.p.t pregnancy tests beginning in June 2004 and continuing for five years.. Our competitors for the sale of fertility/ovulation prediction tests include Armkel, Princeton BioMeditech, Syntron and Quidel. Competition among branded consumer diagnostic products is based on brand recognition and price. Products sold under well-established or "premium" brand names can demand higher prices and maintain high market shares due to brand loyalty. Our Clearblue brand qualifies as a premium brand worldwide with respect to both pregnancy tests and fertility/ovulation prediction products. Our Clearblue pregnancy tests are market leaders outside of the United States, and our Clearblue fertility/ovulation prediction products are market leaders both in the United States and globally. Our Fact plus and Accu-Clear branded consumer products compete based on price and do not attempt to compete based on brand recognition. For private label manufacturers, competition is based primarily on the delivery of products at lower prices that have substantially the same features and performance as brand name products. The Clearblue Fertility Monitor and Persona are

unique products and their competitors or markets are not easily defined.

Certain of our competitors have substantially greater financial, production, marketing and distribution resources than we do. However, we believe that we can continue to compete effectively in the consumer diagnostics market based on our research and development capabilities, advanced manufacturing expertise, diversified product positioning, global market presence and established wholesale and retail distribution networks.

Vitamins and Nutritional Supplements. The market for private label vitamins and nutritional supplements is extremely price sensitive, with quality, customer service and marketing support also being important. Many of the companies that mass market branded vitamins and nutritionals, including NBTY, Pharmavite, Leiner Health Products, and Bayer, also sell to private label customers and constitute our major competitors for private label business. In addition, there are several companies, such as Perrigo and Contract Pharmacal, that compete only in the private label business.

In the branded nutritional supplements industry, competition is based upon brand name recognition, price, quality, customer service and marketing support. There are many companies, both small and large, selling vitamin products to retailers. A number of these companies, particularly manufacturers of nationally advertised brand name products, are substantially larger than we are and have greater financial resources. Among the major competitors of our branded products that are sold through groceries and other mass retailers are NBTY, Wyeth, Pharmavite, Leiner Health Products and GlaxoSmithKline.

Professional Diagnostic Products

In the rapid membrane market, our main competitors are Becton Dickinson, Quidel and Beckman Coulter. Some competitors in this market, such as Becton Dickinson are large companies with greater resources than we have. Other competitors in some product segments are small but aggressive companies such as Syntron Bioresearch, Princeton BioMeditech, VEDA.LAB and Trinity Biotech. Some automated immunoassay systems can be considered competitors when labor shortages force laboratories to automate or when the costs of such systems are lower. Such systems are provided by Abbott, Bayer, Roche Diagnostics, Beckman Coulter and other large diagnostic companies. In the infectious disease area, new technologies utilizing amplification techniques for analyzing molecular DNA gene sequences from companies such as Abbott, Roche and Gen-Probe are making in-roads into this market. Competition in this market is intense and is primarily based on price, breadth of line and distribution capabilities.

Our competitors in the ELISA diagnostics market include large corporations, such as Abbott Laboratories and Diagnostic Products Corporation, which manufacture state-of-the-art automated immunoassay systems and a wide array of diagnostic products designed for processing on those systems. These entities benefit from economies of scale and have the resources to design and manufacture state-of-the-art automated equipment. Other competitors in this market, DiaSorin and Diamedics, in particular, are more similar in size to us and compete based on quality and service. In the United States and Canada, we focus on matching the instrumentation and product testing requirements of our customers by offering a wide selection of diagnostic products and test equipment. Our ImmunoComb product line, which consists of manual tests sold to small laboratories and point-of-care locations, competes against automated ELISA systems based on price.

The markets for our serology and our IFA and microbiology products are mature, and competition is based primarily on price and customer service. Our main competitors in serology and microbiology testing include Med-Ox Diagnostics, Biokit and Quidel. Our main competitors in IFA testing are Bio-Rad Laboratories, INOVA Diagnostics, Immuno Concepts, The Binding Site and DiaSorin. However, products in these categories also compete to a large extent against rapid membrane and ELISA products, which are often easier to perform and read and can be more precise.

Patents and Proprietary Technology; Trademarks

The medical products industry, including the diagnostic testing industry, places considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend, in part, on our abilities to obtain enforceable patent protection for our products, to preserve our trade secrets and to avoid or neutralize threats from the proprietary rights of third parties. We have already built a strong intellectual property portfolio in the area of lateral flow immunoassays, the technology which underlies many rapid diagnostic test formats including most one step home pregnancy and fertility/ovulation tests. By the judicious use of acquisition and strategic licensing we have obtained rights to the major patent families in this area of technology. We believe that these intellectual property rights give us a distinct advantage over our competitors and underpin our continuing success in this area.

In addition to providing us with the rights we need to the lateral flow technology underlying so many of our current products, our intellectual property portfolio also includes an increasing number of other patents, patent applications and licensed patents protecting our vision of the technologies and products of the future. We cannot, however, guarantee our success or timeliness in obtaining future patents or licensed patents or as to the breadth or degree of protection that such patents might afford us. As evidenced in the area of lateral flow immunoassays, the patent position of medical products and diagnostic testing firms is often highly complex and requires resolution of significant legal and factual questions. We endeavor to secure commercially relevant patent and other protection for our technology in a timely manner in meaningful jurisdictions. There are, however, a number of factors that affect our activities and over which we do not have control, such as the workload at the individual patent offices and the policies applied by the patent offices during examination. Consequently, we cannot guarantee that patents will be issued on our technology or, if issued, will be of sufficient breadth so as to prevent competition from third parties.

The medical products industry, including the diagnostic testing industry, historically has been characterized by extensive litigation regarding patents, licenses and other intellectual property rights. We believe that our recent successes in enforcing our intellectual property rights in the United States and abroad demonstrate our resolve in enforcing our intellectual property rights, the strength of our intellectual property portfolio and the competitive advantage that we have in this area. We have incurred substantial costs both in asserting infringement claims against others and in defending ourselves against patent infringement claims, and we expect to incur substantial litigation costs as we continue to aggressively protect our technology and defend our proprietary rights. We currently have

approximately fifteen suits pending against parties whom we believe manufacture or sell products that infringe our patents. To determine the priority of inventions, we may also have to participate in interference proceedings declared by the U.S. Patent and Trademark Office or foreign patent and trademark authorities, which could also result in substantial costs to us. If the outcome of any such litigation is adverse to us, our business could be materially adversely affected.

In addition, we sometimes obtain licenses to patents or other proprietary rights of third parties to manufacture and market our products. We cannot assure you that licenses required under any such patents or proprietary rights would be made available on terms acceptable to us, if at all. If we do not obtain such licenses, we may encounter delays in product market introductions while we attempt to design around such patents or other rights, or we may be unable to develop, manufacture or sell such products in certain countries, or at all.

We also seek to protect our proprietary technology, including technology that may not be patented or patentable, in part through confidentiality agreements and, if applicable, inventors' rights agreements with collaborators, advisors, employees and consultants. We cannot assure you that these agreements will not be breached, that we will have adequate remedies for any breach or that our trade secrets will not otherwise be disclosed to, or discovered by, competitors or potential competitors. Moreover, we may from time to time conduct research through academic advisors and collaborators who are prohibited by their academic institutions from entering into confidentiality or inventors' rights agreements. In such circumstances, our ability to protect our proprietary developments may be limited.

Finally, we believe that certain of our trademarks are valuable assets that are important to the marketing of our products. Substantially all of these trademarks have been registered with the United States Patent and Trademark Office or internationally, as appropriate. We cannot assure you, however, that registrations will afford us adequate protection and will not be challenged as unenforceable or invalid, or will not be infringed. In addition, we could incur substantial costs in defending suits brought against us or in prosecuting suits in which we assert rights under such registrations.

Government Regulation

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation by numerous governmental authorities in the United States and other countries. Most of our self-test products require governmental approvals for commercialization. Future products may require pre-clinical and clinical trials. Manufacturing and marketing of many of our products are subject to the rigorous testing and approval process of the FDA and corresponding foreign regulatory authorities. The marketing of our consumer diagnostic products is also subject to regulation by the U.S. Federal Trade Commission, or the FTC. Data obtained from pre-clinical and clinical activities are susceptible to varying interpretations that could delay, limit or prevent regulatory approval. In addition, we may encounter delays or rejection as a result of changes in, or additions to, regulatory policies for device marketing authorization during the period of product development and regulatory review. Delays in obtaining such approvals could adversely affect our marketing of products developed and our ability to generate commercial product revenues.

In addition, we are required to meet regulatory requirements in countries outside the United States, which can change rapidly with relatively short notice, resulting in our products being banned in certain countries and an associated loss of revenues and income. Foreign regulatory agencies can also introduce test format changes which, if we do not quickly address, can result in restrictions on sales of our products. Such

changes are not uncommon due to advances in basic research.

The manufacturing, processing, formulation, packaging, labeling and advertising of our nutritional supplements are subject to regulation by one or more federal agencies, including the FDA, the U.S. Drug Enforcement Administration, or DEA, the FTC and the Consumer Product Safety Commission. These activities are also regulated by various agencies of the states, localities and foreign countries in

which our nutritional supplements are now sold or may be sold in the future. In particular, the FDA regulates the safety, manufacturing, labeling and distribution of dietary supplements, including vitamins, minerals and herbs, as well as food additives, over-the-counter and prescription drugs and cosmetics. The Good Manufacturing Practices promulgated by the FDA are different for nutritional supplement, drug and device products. In addition, the FTC has jurisdiction along with the FDA to regulate the promotion and advertising of dietary supplements, over-the-counter drugs, cosmetics and foods.

Product Liability and Limited Insurance Coverage

The testing, manufacturing and marketing of consumer and professional diagnostic devices entail an inherent risk of product liability claims. In addition, the marketing of our vitamins and nutritional supplements may subject us to various product liability claims, including, among others, claims that our products 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. There can be no assurance that existing insurance can be renewed at a cost and level of coverage comparable to that presently in effect, if at all. In the event that we are held liable for a claim, against which we are not indemnified or for damages exceeding the limits of our insurance coverage, such liability could have a material adverse effect on our business, financial condition and results of operations.

Employees

As of March 1, 2004, we had a total of 1,435 full-time employees, of which 641 employees are located in the United States. In addition, we utilize the services of a number of consultants specializing in research and development in our targeted markets, regulatory compliance, strategic planning, marketing and legal matters.

ITEM 2. DESCRIPTION OF PROPERTY

Our principal corporate administrative office, together with the administrative office for most of our United States operations, are housed in approximately 20,600 square feet of leased space located at 51 Sawyer Road, Waltham, Massachusetts at a monthly rent of approximately $43,000. Our lease of this facility has a term of five years and expires on May 31, 2008.

Our European operations are currently administered from a 150,000 square foot facility located in Bedford, England. The Bedford facility is also currently providing the manufacturing for our Clearblue and Clearview products, as well as for the pregnancy test products that we manufacture for Pfizer. It also serves as our primary research and development center. This facility contains fully automated assembly equipment, and state-of-the-art research laboratories, with capacity to support potential future expansion. 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 Unilever's lease, Unilever is not permitted to assign the lease to us or sublet the Bedford facility to us without obtaining the prior written consent of the landlord (which consent may not be unreasonably withheld). The landlord has indicated that it will not consent to an assignment of the lease to us, and we, Unilever and the landlord are therefore currently negotiating the terms of a sublease. The terms of our acquisition of the Unipath business in 2001 obligate Unilever to use its best efforts to obtain the landlord's consent to assignment or a sublease and, if necessary, to pursue the assignment or sublease through the courts. Unilever has also agreed to permit us to use the Bedford facility until such time as the lease is assigned to us or the facility is subleased to us by Unilever for the remaining term of the lease, which expires on December 11, 2021. Under the terms of this agreement, we are required to pay all amounts owed under the lease and otherwise comply with the terms of the lease. The annual rent for the Bedford facility is currently £1.46 million (approximately, $2.6 million) and is upwardly adjustable every five years, with the next

adjustment to take place in September 2006. If Unilever is unable to successfully assign the lease to us or otherwise enable us to realize the benefit of its lease of the Bedford facility, we may be forced to renegotiate a lease of this facility on substantially less favorable terms, seek alternative, more costly means of producing our products or suffer other adverse effects to our business.

We also have manufacturing operations in Freehold, New Jersey, Irvington, New Jersey, San Diego, California, Seattle, Washington, Galway, Ireland and Yavne, Israel. We own a 160,000 square foot manufacturing facility in Freehold, New Jersey and lease a 35,000 square foot facility in Irvington, New Jersey. The Irvington lease has a current term of 5 years expiring on December 31, 2006, with an option to extend for an additional 5 years, and the monthly rent is currently approximately $18,100. The New Jersey facilities manufacture our vitamin and nutritional supplement products that we sell to private label customers, to third parties in bulk and under our own brands. ABI currently manufactures its professional diagnostic products, as well as Fact plus for sale in the United States, out of a 40,000 square foot leased facility in San Diego, California. This lease expires on November 30, 2004, and we have options to extend the lease for two consecutive five-year periods. Monthly rent for the San Diego facility is approximately $36,700.

We currently manufacture a portion of our Ostex products in Galway, Ireland. The remainder of these products are currently manufactured in a facility that we lease in Seattle, Washington, although we expect that during the first half of 2004 we will move the manufacturing of these products to a third party manufacturer. Our lease of the first Seattle facility, which consists of approximately 6,800 square feet of manufacturing space and approximately 24,500 square feet of office and laboratory space, expires on October 1, 2005. Our current monthly rent for this facility of approximately $43,300 is partially offset by monthly rental income of approximately $12,400 from several subleases of portions of the office and laboratory space. We also have a second manufacturing facility in Seattle that we are no longer using which carries monthly rent of approximately $9,000 and is the subject of a ten year lease expiring September 30, 2010. Our facility in Galway, Ireland consists of a 40,000 square foot space. We own half of the Galway facility and lease the other half from a private developer under a lease that expires in 2026. The Galway facility also houses the manufacturing of our Accu-Clear brands and most of our private label pregnancy detection and fertility/ovulation prediction test products, as well as some research and development. Annual lease payments for our Galway facility are approximately $230,000.

We also house the development, manufacturing, administrative and marketing operations related to our Orgenics professional diagnostic products in a leased facility of approximately 10,000 square feet in Yavne, Israel. The lease for this facility expires in 2008, and carries rent of approximately $15,000 per month. The facility includes a number of specialized features and equipment, including environmentally controlled areas, customized production equipment, and computerized systems for purchasing, inventory management and materials tracking.

We also have leases or other arrangements for administrative offices, lab space and warehouses in New Jersey (Freehold, Springfield, Irvington and Princeton), California (San Diego), Denmark (Farum), Belgium (Sint-Niklaas), Germany (Cologne) and Sweden (Lund), and our Orgenics products are sold through small sales offices in France, Brazil and several other countries. We believe that our facilities, along with certain third party manufacturing, packaging and distribution arrangements that we utilize, are adequate to support the operations of our businesses in the foreseeable future. We have insurance coverage for the properties and equipment that we own or lease.

ITEM 3. LEGAL PROCEEDINGS

Inverness Medical Switzerland GmbH, et al. v. Pfizer Inc., et al.

We previously had several lawsuits pending against Pfizer Inc. and certain other parties, including Princeton BioMeditech, or PBM, in the United States District Court for the District of New Jersey alleging, among other things, that pregnancy tests manufactured or sold by the defendants infringe patents owned by us. In early June 2003, we settled our litigation against Pfizer. However, our claims against PBM, a co-defendant in one of the infringement suits against Pfizer and the subject of two other related infringement suits initiated by us, remain active. PBM has brought several counterclaims against us. The counterclaims allege, among other things, that we have breached various obligations to PBM arising out of a joint venture with us. We believe that we have strong defenses to all of the counterclaims and we are defending them vigorously.

Quidel Corporation v. Inverness Medical Innovations, Inc., et al.

In February 2004, Quidel Corporation was served in Germany with a suit that our subsidiary, Inverness Medical Switzerland, GmbH (IMS), had filed in January 2004 seeking damages and injunction for infringement of certain of our patents. In response, on February 20, 2004, Quidel named us and our subsidiaries IMS and ABI as defendants in a suit filed by Quidel in the United States District Court for the Southern District of California. Quidel alleges that we are infringing U.S. Patent No. 4,943,522, a patent that issued in 1990 titled "Lateral Flow, Non-Bibulous Membrane Assay Protocols." Quidel also asked the Court for a declaratory finding that Quidel does not infringe certain patents owned by IMS

and certain other patents owned by co-defendant Armkel LLC, collectively the "Patents," and that the Patents are invalid and/or unenforceable. Quidel seeks injunctive relief and damages, and has indicated its intent to file a motion for preliminary injunction, the scope of which has not been disclosed. In early March, 2004, we filed an answer claiming that Quidel's claims are without merit and a counterclaim seeking damages and injunctive relief for Quidel's infringement of the Patents. We also filed a separate action against Quidel in the same court alleging infringement of certain other patents and seeking injunctive relief and damages. We intend to vigorously defend the Quidel claims and vigorously prosecute the infringement counterclaims and separate claims to enforce our own intellectual property rights.

Other Pending and Potential Litigation and Proceedings

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. Such lawsuits generally seek damages, sometimes in substantial amounts, for personal injuries or other commercial or employment claims. An adverse ruling in such a lawsuit could 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. We have approximately 15 lawsuits pending around the world against competitors whom we believe to be selling products that infringe our propriety rights, including a suit against Acon Laboratories. These suits can be expensive and result in counterclaims challenging the validity of our patents and other rights.

We have discussed in prior periodic reports an action in London by approximately 65 consumers claiming defects in Unipath's Persona contraceptive device, negligence and breach of contract, all allegedly leading to unwanted pregnancies by the claimants in or prior to 1998. Because this 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, we do not

believe that an adverse ruling against us would have a material adverse impact on our sales, operations or financial performance and we do not consider this to be a material legal proceeding.

In October 2003, in connection with an informal inquiry received from the SEC's Division of Enforcement, we met with two representatives of the SEC's Boston office to respond to questions regarding the resignation of Ernst & Young LLP, our former auditor, and certain of the accounting and financial matters that we discussed with the SEC during the second quarter of 2003 after filing our Current Report on Form 8-K, event date April 11, 2003, to disclose Ernst & Young's resignation. We responded fully to the staff's request for information. On January 28, 2004, in connection with its ongoing informal investigation, we received a request from the staff of the SEC for some additional factual information as a follow-up to our prior response. We have responded fully to this request for additional information. We cannot predict whether the SEC will seek additional information or what the outcome of the informal investigation will be.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

No matters were submitted to a vote of our security holders during the fourth quarter of the year ended December 31, 2003.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Our common stock trades on the American Stock Exchange (AMEX) under the symbol "IMA." The following table sets forth the high and low closing sale prices of our common stock on AMEX for each quarter during fiscal 2003 and fiscal 2002.

	High	Low

Fiscal 2003		
Fourth Quarter	$ 27.50	$ 20.50
Third Quarter	$ 25.68	$ 19.10
Second Quarter	$ 20.75	$ 15.25
First Quarter	$ 20.14	$ 13.40
Fiscal 2002		
Fourth Quarter	$ 15.35	$ 8.00
Third Quarter	$ 18.90	$ 9.49
Second Quarter	$ 28.21	$ 17.45
First Quarter	$ 25.41	$ 18.00

On March 12, 2004, there were 504 holders of record of our common stock. The closing price of our common stock on March 12, 2004 was $20.75.

We have never declared or paid any cash dividends on our common stock. We currently intend to retain earnings to support our growth strategy and do not anticipate paying cash dividends on our common stock in the foreseeable future. Payment of future dividends, if any, on our common stock will be at the discretion of our board of directors after taking into account various factors, including our financial condition, operating results, current and anticipated cash needs and plans for expansion. In addition, restrictive covenants under our senior credit facility and the indenture governing the terms of the senior subordinated notes currently prohibit the payment of cash or stock dividends.

On November 18, 2003, we issued 93,214 shares of unregistered common stock to NKT Holding A/S as partial consideration for the acquisition by our subsidiary, Inverness Medical Switzerland GmbH, of the entire share capital of Scandinavian Micro Biodevices A/S. No underwriters or underwriting discounts or commissions were involved. There was no public offering in connection with our sale to NKT Holdings and we believe that the transaction was exempt from the registration requirements of the Securities Act of 1933, as amended, pursuant to Section 4(2) thereof, based on the private nature of the transaction, because we understand NKT Holdings to be an accredited investor and because NKT Holdings acquired the securities for investment purposes and not with a view to the distribution thereof.

On December 11, 2003, we issued 230,000 shares of common stock upon conversion of 115,000 shares of our series A redeemable convertible preferred stock pursuant to an exemption afforded by Section 3(a)(9) of the Securities Act of 1933, as amended.

ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following tables provide selected consolidated financial data of our company as of and for each of the years in the five-year period ended December 31, 2003 and should be read in conjunction with our consolidated financial statements and notes included elsewhere in this Annual Report on Form 10-K.

The selected consolidated financial data as of and for each of the years in the three-year period ended December 31, 2003 have been derived from our consolidated financial statements which are included elsewhere in this Annual Report on Form 10-K. The information as of and for the years ended December 31, 2003 and 2002 included in our consolidated financial statements was audited by BDO Seidman, LLP, independent auditors, while the information for the year ended December 31, 2001 included in our consolidated financial statements was audited by Arthur Andersen LLP, independent public accountants. The selected consolidated financial data as of December 31, 2001, 2000 and 1999 and for the years ended December 31, 2000 and 1999 have been derived from our audited consolidated financial statements not included herein, which were audited by Arthur Andersen LLP.

On November 21, 2001, our company was split-off as an independent public company as part of a split-off and merger transaction whereby Johnson & Johnson acquired our former parent company, Inverness Medical Technology, Inc., or IMT. As part of the split-off and merger, we acquired all rights to IMT's women's health, nutritional supplement and professional diagnostics businesses, as well as certain intellectual property. Because we had not historically been operated or accounted for as a stand-alone business, the financial results for the periods prior to the split-off on November 21, 2001, presented below in the selected consolidated financial data, are derived from consolidated financial statements of our businesses, which have been carved out of IMT's financial statements in accordance with the requirements of accounting principles generally accepted in the United States of America, or GAAP. Because the financial results for the periods prior to the split-off have been carved out of IMT's past financial statements, they may not reflect what our results of operations and financial position would have been had we been a separate stand-alone entity during those periods or be indicative of our future performance. In addition, the acquisitions of the Unipath business in December 2001, IVC Industries, Inc. (now operating as Inverness Medical Nutritionals Group, or IMN) in March 2002, Wampole Laboratories in September 2002, Ostex International, Inc. in June 2003, ABI in August 2003 and the Abbott rapid diagnostics product lines in September 2003 materially affected the comparability of the selected consolidated financial data. For a discussion of certain factors that materially affect the comparability of the selected consolidated financial data or cause the data reflected herein not to be indicative of our future results of operations or financial condition, see Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Certain Factors Affecting Future Results."

We have made certain restatements to our consolidated financial statements as of and for the years ended December 31, 2003 and 2002. For a discussion of the restatements, see "Explanatory Note" on page 2, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" and note 2(q) of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

(in thousands, except per share data)

	2003	2002(2)	2001	2000	1999
	(restated)	(restated)			
Statement of Operations Data:					
Net product sales	$ 286,984	$ 200,399	$ 47,268	$ 49,728	$ 49,087
License revenue	9,728	6,405			
Net revenue	296,712	206,804	47,268	49,728	49,087
Cost of sales	168,120	114,653	26,662	26,796	28,348
Gross profit	128,592	92,151	20,606	22,932	20,739
Operating expenses:					
Purchased in-process research and development			6,980		
Research and development	24,280	14,471	1,810	1,360	1,395
Sales and marketing	51,705	39,544	8,018	7,540	8,056
General and administrative	35,452	28,066	11,702	7,048	7,214
Charge related to asset impairment		12,682			
Stock-based compensation	447	10,625	10,441		
Total operating expenses	111,884	105,388	38,951	15,948	16,665
Operating income (loss)	16,708	(13,237)	(18,345)	6,984	4,074
Interest and other income (expense), net	(3,270)	(5,955)	(4,310)	(2,423)	(2,710)
Income (loss) from continuing operations before income taxes	13,438	(19,192)	(22,655)	4,561	1,364
Provision for income taxes	1,169	2,683	2,134	1,781	1,007
Income (loss) from continuing operations	$ 12,269	$ (21,875)	$ (24,789)	$ 2,780	$ 357
Income (loss) from continuing operations available to common stockholders(1):					
Basic(1)	$ 11,311	$ (33,823)	$ (24,789)	$ 2,780	$ 357
Diluted(1)	$ 11,491	$ (33,823)	$ (24,789)	$ 2,780	$ 357
Income (loss) from continuing operations per common share(1):					
Basic(1)	$ 0.72	$ (3.40)	$ (3.89)	$ 0.59	$ 0.11
Diluted(1)	$ 0.64	$ (3.40)	$ (3.89)	$ 0.59	$ 0.11
Other Financial Data:					
EBITDA(3)	$ 37,691	$ 4,762	$ (17,505)	$ 9,303	$ 6,325
			December 31,		

	December 31,				
	2003	2002	2001	2000	1999
		(restated)			
Balance Sheet Data:					
Cash and cash equivalents	$ 24,622	$ 30,668	$ 52,024	$ 3,071	$ 661
Working capital (deficit)	45,220	27,685	19,555	(6,464)	(4,060)
Total assets	543,468	357,255	278,521	74,958	72,210
Total debt	176,181	104,613	78,124	12,830	19,076
Redeemable convertible preferred stock	6,185	9,051	51,894		
Total stockholders' equity	269,549	162,609	89,614	41,812	34,953

(1)

Income (loss) available to common stockholders and basic and diluted income (loss) per share are computed as described in notes 1, 2(k) and 11 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

(2)

Upon the adoption of Statement of Financial Accounting Standards, or SFAS, No. 142, *Goodwill and Other Intangible* Assets, on January 1, 2002, we recorded an impairment charge of $12.1 million, or $1.22 per basic and diluted share, and accounted for the charge as a cumulative effect of a change in accounting principal which was subtracted from loss from continuing operations to arrive at net loss. Consequently, net loss available to common stockholders in 2002 was $46.0 million, or $4.62 per basic and diluted share.

(3)

EBITDA represents income (loss) from continuing operations before interest, income taxes, depreciation and amortization. EBITDA is presented because we believe that it is a useful indicator of our performance and ability to meet debt service and capital expenditure requirements. It allows investors and management to evaluate and compare our operating results from continuing operations from period to period in a meaningful and consistent manner in addition to standard financial measurements under GAAP. Management internally evaluates the performance of its businesses using EBITDA measures. EBITDA is not a measurement of financial performance under GAAP and should not be considered as an alternative to cash flow from operating activities or net income, as a measure of liquidity or as an indicator of operating performance or any measure of performance derived in accordance with GAAP. Our calculation of EBITDA may be different from the calculation used by other companies and, accordingly, comparability may be limited. In addition, our calculation of EBITDA is different than that used in the covenants concerning our primary senior credit facilities and the definition of consolidated cash flow used in the indenture governing the senior subordinated notes that were issued on February 10, 2004.

Set forth in the table below is a reconciliation of income (loss) from continuing operations to EBITDA:

	(in thousands)				
	2003	2002	2001	2000	1999
	(restated)	(restated)			
Income (loss) from continuing operations	$ 12,269	$ (21,875)	$ (24,789)	$ 2,780	$ 357
Interest expense, net of interest income	8,668	13,646	1,909	2,008	2,118
Income taxes	1,169	2,683	2,134	1,781	1,007
Depreciation and amortization	15,585	10,308	3,241	2,734	2,843
EBITDA	$ 37,691	$ 4,762	$ (17,505)	$ 9,303	$ 6,325

Income (loss) from continuing operations includes the following non-cash or unusual items. No adjustment to EBITDA has been made for these items.

	(in thousands)				
	2003	2002	2001	2000	1999
Non-cash stock-based compensation	$ 447	$ 10,625	$ 10,441	$	$
Settlement with Unilever	(3,803)				
Impairment of intangible assets		12,682			
Gain from repurchase of beneficial conversion feature		(9,600)			
Purchased in-process research and development charge			6,980		
Total non-cash and unusual items	$ (3,356)	$ 13,707	$ 17,421	$	$

Effect of the adoption of Statement of Financial Accounting Standard, or SFAS, No. 142, "Goodwill and Other Intangible Assets"

On January 1, 2002, we adopted SFAS No. 142 and, accordingly, no longer amortize goodwill and other intangible assets with indefinite lives, but rather such assets are subject to annual impairment reviews or more frequently, if events or circumstances indicate that they may be impaired. During the first quarter of 2002, we completed the implementation review as required under SFAS No. 142 and recorded an impairment of goodwill related to our nutritional supplements reporting unit in the amount of $12.1 million, which we accounted for as a cumulative effect of a change in accounting principle in our consolidated statement of operations in that period. The following table presents the income (loss) from continuing operations data of our company, as if no amortization of goodwill was recorded under SFAS No. 142 for all periods presented.

(in thousands, except per share data)

	Year Ended December 31,				
	2003	2002	2001	2000	1999
	(restated)	(restated)			
Income (loss) from continuing operations	$ 12,269	$ (21,875)	$ (24,789)	$ 2,780	$ 357
Add back: Goodwill amortization, net of tax			398	398	557
Adjusted income (loss) from continuing operations	$ 12,269	$ (21,875)	$ (24,391)	$ 3,178	$ 914
Adjusted income (loss) from continuing operations available to common stockholders(1):					
Basic	$ 11,311	$ (33,823)	$ (24,391)	$ 3,178	$ 914
Diluted	$ 11,491	$ (33,823)	$ (24,391)	$ 3,178	$ 914
Adjusted income (loss) from continuing operations per common share(1):					
Basic	$ 0.72	$ (3.40)	$ (3.83)	$ 0.67	$ 0.27
Diluted	$ 0.64	$ (3.40)	$ (3.83)	$ 0.67	$ 0.27

(1) Income (loss) available to common stockholders and basic and diluted income (loss) per share are computed as described in notes 1, 2(k) and 11 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

General

We are a leading global developer, manufacturer and marketer of in vitro diagnostic products for the over-the-counter pregnancy and fertility/ovulation test market and the professional rapid diagnostic test market. Our business is organized into two primary segments, consumer products and professional diagnostics. Through our consumer products segment, we hold a leadership position in the worldwide over-the-counter pregnancy and fertility/ovulation test market. We sell our pregnancy and fertility/ovulation test products in the premium branded sector, the value branded sector and the private label sector. In addition, we manufacture and market a variety of vitamins and nutritional supplements under our brands and those of private label retailers primarily in the U.S. consumer market. Through our professional diagnostics segment, we develop, manufacture and market an extensive array of innovative rapid diagnostic test products and other in vitro diagnostic tests to medical professionals and laboratories for detection of infectious diseases, drugs of abuse and pregnancy. Today, we are a leader in the worldwide professional rapid diagnostic test market. We have grown our consumer products and professional diagnostics segments by leveraging our strong intellectual property portfolio and making selected strategic acquisitions. Our consumer and professional diagnostic products are sold in approximately 90 countries through our direct sales force and an extensive network of independent global distributors. As a result, for the year ended December 31, 2003, approximately 36% of our net product sales were generated outside of the United States. For the year ended December 31, 2003, we had net product sales of $287.0 million and EBITDA of $37.7 million.

Our consumer products segment accounted for 69% of our net product sales for the year ended December 31, 2003 and primarily targets the women's health market through home pregnancy detection tests and home fertility/ovulation prediction tests. Approximately 81% of our net product sales in the over-the-counter women's health market in 2003 were sales of our own branded products while the remaining represented

sales under private label and contract manufacturing arrangements. We have entered into two separate supply arrangements with Pfizer pursuant to which we began to

supply Pfizer a digital version of its e.p.t pregnancy tests on a non-exclusive basis in December 2003 and agreed to also supply Pfizer with the non-digital version of its premium branded e.p.t pregnancy tests beginning in June 2004 and continuing for five years. As a part of our consumer products segment, we also market a wide variety of vitamins and nutritional supplements through retail drug stores, mass merchandisers, groceries and warehouse clubs, primarily within the United States. Sales of these products accounted for 25% of our net product sales for the year ended December 31, 2003.

Our professional diagnostics segment, which accounted for 31% of our net product sales for the year ended December 31, 2003, consists of diagnostic test products designed to assist medical professionals in both preventative and interventional medicine. We are currently focusing a significant portion of our research and development efforts in the area of cardiology.

Our History

On November 21, 2001, Johnson & Johnson acquired IMT, our former parent, in a merger transaction and, simultaneously, our company 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 would hold all of IMT's non-diabetes businesses, including women's health, nutritional supplements and clinical diagnostics. At the closing of the transaction, 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 of its diabetes business) merged with and became a wholly-owned subsidiary of Johnson & Johnson.

On December 20, 2001, we acquired Unipath Limited, a global leader in home pregnancy and ovulation testing, and its associated companies and assets from Unilever plc and certain affiliated entities. The Unipath acquisition provided us with leading brand name consumer diagnostic products that complement our existing value branded and private label home pregnancy detection and fertility/ovulation prediction products. In connection with the acquisition of the Unipath business, we also acquired rights to certain antibody clones and other intellectual property rights.

On March 19, 2002, we acquired IVC Industries, Inc., a manufacturer and distributor of hundreds of different vitamin and nutritional supplement products sold under brand names and through private label arrangements with retailers. Since our acquisition of IVC, we have consolidated substantially all of our vitamin and nutritional supplement manufacturing at IVC and discontinued most of our outsourced manufacturing arrangements. IVC is now doing business as Inverness Medical Nutritionals Group, or IMN.

On September 20, 2002, we acquired the Wampole Laboratories division of MedPointe Inc., a developer, marketer, seller and distributor of in vitro diagnostic tests and test systems. Wampole is a leader in enzyme linked immunosorbent assay, or ELISA, testing within the professional laboratory marketplace and also offers a broad line of visually-read assays for point-of-care testing. Wampole's products are sold to hospitals, major reference testing laboratories, physicians' offices and clinics through an extensive U.S. distribution network and these products compliment our existing professional diagnostic products lines and international distribution networks.

On June 30, 2003, we acquired Ostex International, Inc., which develops and commercializes osteoporosis diagnostic products. This acquisition provides us with intellectual property rights in the field of osteoporosis diagnostics.

On August 27, 2003, we acquired Applied Biotech, Inc. from Apogent Technologies Inc. ABI is a developer, manufacturer and distributor of rapid diagnostic products in the areas of women's health, infectious disease and drugs of abuse testing. In the transaction, we also acquired ABI's wholly-owned subsidiary, Forefront Diagnostics, Inc. Forefront develops, manufactures and distributes rapid diagnostic products for drugs of abuse testing.

On September 30, 2003, we acquired from Abbott Laboratories certain assets related to Abbott's Fact plus line of consumer diagnostic pregnancy tests and Abbott TestPack, Abbott TestPack plus and Signify lines of professional rapid diagnostics for various testing needs, including strep throat, pregnancy and drugs of abuse. The acquired assets also include certain transferred and licensed intellectual property related to these products.

On February 10, 2004, we completed the sale of $150.0 million of 8 3/4% senior subordinated notes, or Bonds, due 2012 in a private placement to qualified institutional buyers. Net proceeds from this offering amounted to $145.9 million which was net of underwriters' commissions of $4.1 million. Of the net proceeds, we used $125.3 million to repay all of our outstanding indebtedness and related financing fees under our primary senior credit facility and $9.2 million to prepay our outstanding 9% subordinated promissory notes and related prepayment penalties. The remaining $11.4 million of unused proceeds will be used for Bond offering expenses and general corporate purposes. We also retained the $50.0 million in available credit under our primary senior credit facility after our repayment of the outstanding borrowings using the Bond proceeds.

Restatements of 2003 and 2002 Financial Statements

We restated our previously issued consolidated financial statements as of and for the year ended December 31, 2002 to reverse a realized foreign exchange gain of $2.6 million related to the repayment of a portion of a long-term intercompany loan that had previously been reported in other income (expense), net, and to instead reflect the change in value of the intercompany loan prior to repayment as a component of accumulated other comprehensive income. In connection with this restatement, we also restated our previously issued consolidated financial statements for the quarterly impacts of certain adjustments related to sales cut-off and sales incentive allowances, the effects of which on operating results had previously been corrected in the periods in which they had been identified rather than in the periods to which they related. See "Supplementary Quarterly Financial Information" beginning on page 37 in this report for a comparison of the restated quarterly amounts to previously reported quarterly amounts.

The following lists the accounts shown in Item 6 "Selected Consolidated Financial Data" of this Annual Report on Form 10-K, that were affected by the restatements discussed above, with comparisons of the restated to previously reported amounts, and the effect of such restatements on gross profit, income (loss) from continuing operations, earnings (loss) per share and EBITDA. See note 2(q) of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for a detail comparison of the restated amounts to previously reported amounts.

(in thousands, except per share data)

	2003	
	As restated	As reported
Net product sales	$ 286,984	$ 286,689
Gross profit	128,592	128,297
Income (loss) from continuing operations	12,269	11,974
Income (loss) from continuing operations per common share(1):		
Basic	$ 0.72	$ 0.70
Diluted	$ 0.64	$ 0.63
EBITDA	$ 37,691	$ 37,396

	2002	
	As restated	As reported
Net product sales	$ 200,399	$ 201,641
Cost of sales	114,653	115,600
Gross profit	92,151	92,446
Interest and other income (expense), net	(5,955)	(3,362)
Income (loss) from continuing operations	(21,875)	(18,987)
Income (loss) from continuing operations per common share(1):		
Basic	$ (3.40)	$ (3.11)
Diluted	$ (3.40)	$ (3.11)
EBITDA	$ 4,762	$ 7,650

	December 31, 2002	
	As restated	As reported
Working capital	$ 27,685	$ 27,980
Total assets	357,255	357,746
Total stockholders' equity	162,609	162,904

(1) Income (loss) from continuing operations per common share are computed as described in note 11 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Results of Operations

Year Ended December 31, 2003 Compared to Year Ended December 31, 2002

Net Product Sales. Net product sales increased by $86.6 million, or 43%, to $287.0 million in 2003 from $200.4 million in 2002. Excluding the favorable impact of currency translation, net product sales in 2003 grew by approximately $78.1 million, or 39%, over 2002. The majority of the revenue increase resulted from our acquired businesses: (i) IMN, which we acquired in March 2002, contributed $12.6 million of such increase, (ii) Wampole, which we acquired in September 2002, contributed $33.3 million of such increase, including revenue from certain osteoporosis products acquired as part of our acquisition of Ostex in June 2003, (iii) ABI, which we acquired in August 2003, contributed $9.3 million of such increase, and (iv) the rapid diagnostic product lines from Abbott, which we acquired in September 2003, contributed $11.2 million of such increase. The remaining increase in net product sales from 2002 to 2003, or $11.7 million, primarily represents organic growth, including the launch of our new Clearblue Easy Digital pregnancy test in June 2003, and the commencement of our supply of the digital version of Pfizer's e.p.t pregnancy test in December 2003.

Net Product Sales by Business Segment. Net product sales by business segment for 2003 and 2002 are as follows:

(in thousands)	2003	2002 (restated)	% Increase
Consumer products	$ 198,693	$ 167,359	19%
Professional diagnostic products	88,291	33,040	167%
Total net product sales	$ 286,984	$ 200,399	43%

The increase in net product sales from our consumer products, which includes our consumer diagnostic products and our vitamins and nutritional supplements, from 2002 to 2003 primarily resulted from our acquisition of the IMN business, the organic growth in our women's health care business and the launch of our Clearblue Easy Digital pregnancy test in June 2003. To a lesser extent, our acquisition of Abbott's Fact plus line of consumer diagnostic pregnancy tests contributed to the increase in net product sales from our consumer products. We expect net product sales from our consumer products to increase in 2004, as we continue the launch of our Clearblue Easy Digital pregnancy test and supply of Pfizer's digital and non-digital e.p.t pregnancy tests, the latter of which will begin in June 2004.

The increase in net product sales from our professional diagnostic products from 2002 to 2003 primarily resulted from our acquisitions of Wampole, ABI and the Abbott TestPack, Abbott TestPack plus and Signify product lines from Abbott.

Net Product Sales by Geographic Location. Net product sales by geographic location for 2003 and 2002 are as follows:

(in thousands)	2003	2002 (restated)	% Increase
United States	$ 182,580	$ 106,821	71%
Europe	69,594	67,863	3%
Other	34,810	25,715	35%
Total net product sales	$ 286,984	$ 200,399	43%

The increase in net product sales in the United States from 2002 to 2003 primarily resulted from our acquisitions of the IMN and Wampole businesses, the products of which are primarily sold in the United States, and the launch of our new digital pregnancy tests in the United States. To a lesser extent, our acquisition of the Signify product line from Abbott, which is primarily sold in the United States, contributed to the increase in net product sales in the United States. The increase in net product sales in regions other than United States and Europe from 2002 to 2003 resulted partially from our acquisitions of the Abbott Testpack, Abbott Testpack plus and Fact plus product lines, Ostex and ABI. In addition, IMN and Wampole recorded higher sales in Canada due to these businesses being included in our results for the full year in 2003 versus partial year in 2002 since their respective acquisition dates. The remaining increase in regions other than United States and Europe resulted from organic growth of our business.

License Revenue. License revenue represents license and royalty fees from intellectual property license agreements with third-parties. License revenue increased by $3.3 million, or 52%, to $9.7 million in 2003 from $6.4 million in 2002. The increase largely resulted from royalty fees from Pfizer. Beginning in the third quarter of 2003 and continuing through June 2004, we began to record and collect royalty fees from Pfizer as part of the settlement of our infringement litigation against it. During 2003, we recorded $1.7 million in royalties from Pfizer. The acquisition of Wampole also provided us with additional license agreements which generated $621,000 in license revenue in 2003 compared to

$227,000 in 2002. The remainder of the increase in license revenue resulted from increased sales and minimum royalty payments by certain of our licensees. We expect license revenue in 2004 to decrease, as the revenue stream from one of the significant license agreements ended on December 31, 2003 in accordance with the license agreement. This license agreement provided us with $2.5 million in license revenue in 2003.

Gross Profit from Net Product Sales. Gross profit from net product sales represents total gross profits less gross profits associated with license revenue. Gross profit from net product sales increased by $33.5 million, or 38%, to $122.1 million in 2003 from $88.6 million in 2002. Consistent with the growth in net product sales, the increase of gross profit from net product sales primarily resulted from our acquisitions: (i) Wampole contributed $11.9 million of such increase, (ii) ABI contributed $2.4 million of such increase, and (iii) the rapid diagnostic product lines from Abbott contributed $4.3 million of such increase. The remaining increase in gross profit from net product sales from 2002 to 2003, or $14.9 million, primarily resulted from organic growth, including the launch of our new Clearblue Easy Digital pregnancy test in June 2003, and the commencement of our supply of the digital version of Pfizer's e.p.t pregnancy test in December 2003.

Overall gross margin from net product sales was 43% in 2003 compared to 44% in 2002. Gross margin was adversely impacted in 2003 by the continued weakening of the U.S. Dollar against the Euro and British Pound Sterling. Such movements in foreign exchange currencies negatively impacted the gross margin percentage for our products manufactured at our European subsidiaries and sold in U.S. Dollars. This currency impact had the effect of reducing gross margins by 1.7 percentage points from 2002 to 2003. In addition, the decline in overall gross margin from net product sales from 2002 to 2003 resulted from the Wampole business being included in our 2003 results for the full year, compared to only three months in our 2002 results and the addition of the acquired Abbott products, both of which, on average, have contributed lower gross margins than our other products. The impact of including the Wampole business for the full year and the Abbott business in our 2003 results was a 1.1 percentage point reduction in the overall gross margin percentage. Since we completed the Abbott transaction, Abbott has continued to distribute certain of the acquired products on our behalf and to manufacture certain of the acquired products for us under transition agreements. Over the course of 2004, we will transfer all of the Abbott business to our existing manufacturing and distribution networks and, by doing so, we expect the gross margins on the acquired Abbott products to increase during 2004. Partially offsetting the negative impact to gross margin due to foreign currency movements and the Wampole and Abbott products were sales of our Clearblue Easy Digital pregnancy test in 2003, which generated a higher than average margin as compared to some of our other consumer products.

Gross Profit from Net Product Sales by Business Segment. Gross profit from net product sales by business segment for 2003 and 2002 are as follows:

(in thousands)	2003	2002 (restated)	% Increase
Consumer products	$ 85,487	$ 72,961	17%
Professional diagnostic products	36,637	15,688	134%
Total gross profit from net product sales	$ 122,124	$ 88,649	38%

The increase in gross profit from our consumer product sales from 2002 to 2003 primarily resulted from the organic growth in our women's health care business, including the launch of our Clearblue Easy Digital pregnancy test in June 2003, and our acquisition of Abbott's Fact plus line of consumer diagnostic pregnancy tests. We expect gross profit from our consumer product sales to continue to increase in 2004 as we continue the launch of our Clearblue Easy Digital pregnancy test and supply of Pfizer's digital and non-digital e.p.t pregnancy tests, the latter of which will begin in June 2004. Gross margin from our consumer product sales was 43% and 44% in 2003 and 2002, respectively. Movements

in foreign currencies negatively impacted the gross margin from our consumer product sales by 2.4 percentage points for our products manufactured at our European subsidiaries and sold in U.S. Dollars. The negative impact of foreign currency movements on gross margin from our consumer products was basically offset by the organic growth in our women's health care sales, including the sales of our Clearblue Easy Digital pregnancy test, which generated a higher than average margin as compared to some of our other consumer products.

The increase in gross profit from our professional diagnostic product sales from 2002 to 2003 primarily resulted from our acquisitions of Wampole, ABI and the Abbott TestPack, Abbott TestPack plus and Signify product lines from Abbott. Gross margin of our professional diagnostic products was 41% in 2003 compared to 47% in 2002. The decline in gross margin of our professional diagnostic products primarily resulted from the inclusion of Wampole's business for the full year in 2003, compared to only three months in 2002 because on average the Wampole products generate a lower gross margin than our other products. The professional diagnostic product lines acquired from Abbott that are currently being manufactured or sold by Abbott under transition agreements also generate lower margins than our other products. The effect on gross margin percentage of our professional diagnostic products as a result of the incremental Wampole business due to it being included in our 2003 results for the full year compared to the three month results included in 2002, and the Abbott product lines was a 5% point reduction.

Research and Development Expense. Research and development expense increased by $9.8 million, or 68%, to $24.3 million in 2003 from $14.5 million in 2002. The primary reason for the increase in research and development expense was our heavy investment in the development of new products, particularly in the field of cardiology and infectious diseases. For example, a pro-thrombin test is scheduled for release late 2004, subject to regulatory approvals, and a congestive heart failure product remains on track for launch in 2005. Further, we expect to launch several infectious disease products in 2004, including a high-sensitivity strep throat test, rapid influenza A & B tests and a rapid HIV test. For factors that may impact our ability to meet our expectations to launch these products, see "Certain Factors Affecting Future Results." To a lesser extent, our acquisitions of Ostex and ABI contributed to the increase in research and development expense from 2002 to 2003. We expect the level of research and development expenditure in 2004 to be in the range of $25 million to $26 million.

Sales and Marketing Expense. Sales and marketing expense increased by $12.2 million, or 31%, to $51.7 million in 2003 from $39.5 million in 2002. Of the increase in sales and marketing expense from 2002 to 2003, $4.9 million resulted from Wampole's results being included for the full year in 2003 compared to only three months in 2002. Similarly, the acquisitions of Ostex and ABI contributed $898,000 of the increase in sales and marketing expense. In addition, sales and marketing expense increased due to our organic growth, primarily the launch of our Clearblue Easy Digital pregnancy test.

Sales and marketing expense as a percentage of net product sales decreased to 18% in 2003 from 20% in 2002, which primarily resulted from the Wampole business which incur lower sales and marketing expense as a percentage of sales compared to our other businesses. Further, we have not incurred significant incremental sales and marketing expenses with the addition of the product lines we acquired from Abbott in 2003. We expect to maintain sales and marketing expense at or below 18% of net product sales in 2004.

General and Administrative Expense. General and administrative expense increased by $7.4 million, or 26%, to $35.5 million in 2003 from $28.1 million in 2002. Of the increase in general and administrative expense from 2002 to 2003, $1.9 million resulted from Wampole's results being included for the full year in 2003 compared to only three months in 2002. Similarly, the acquisitions of Ostex and ABI contributed $1.8 million of the increase in general and administrative expense. In addition, a portion of the increase in general and administrative expense resulted from our investment in increased management and infrastructure, higher insurance premiums and our continued significant

investment to pursue legal remedies against potential infringers of our intellectual property. Partially offsetting the increase in general and administrative expense from 2002 to 2003 was the recognition of $554,000 representing a reimbursement by insurance of legal costs previously incurred in connection with the Persona lawsuit, for which we assumed the defense when we acquired the Unipath business in December 2001. In addition, another $187,000 of such recovery of legal costs is included in other income (expense), net, as that portion represented recovery of legal costs incurred prior to our acquisition of the Unipath business. For a further discussion of the Persona lawsuit, see "Item 3. Legal Proceedings" in this Annual Report on Form 10-K.

General and administrative expense as a percentage of net product sales decreased to 12% in 2003 from 14% in 2002. The improvement of general and administrative expense as a percentage of net product sales was achieved through sales increase, the above mentioned legal cost recovery and the addition of the product lines acquired from Abbott, for which we have not incurred significant incremental general and administrative costs in 2003. We expect to maintain general and administrative expense at or around 12% of net product sales in 2004.

Stock-Based Compensation Expense. Stock-based compensation expense was $447,000 in 2003 compared to $10.6 million in 2002. Stock-based compensation expense in 2003 primarily represented a non-cash compensation charge for stock options granted in lieu of salary of certain senior executives. In 2002, the majority of the stock-based compensation charge represented the amortization of deferred compensation expense that arose from a sale of our company's restricted stock made to our chief executive officer at a price below the market value of our stock on the measurement date of the transaction.

Interest Expense. Interest expense includes interest charges, amortization of deferred financing costs and non-cash discounts associated with our debt issuances and the change in market value of our interest rate swap agreement which did not qualify as a hedge for accounting purposes. Interest expense decreased by $5.4 million, or 36%, to $9.7 million in 2003 from $15.1 million in 2002. In 2002, we recorded an aggregate of $4.5 million in amortization of deferred financing costs, non-cash original issue discounts and discounts in the form of a beneficial conversion feature related to early extinguishment of certain subordinated promissory notes and bank debt. Also in 2002, we recorded a non-cash charge of $1.2 million to mark to market our interest rate swap agreement that was entered into early 2002. During 2003, the market value of our obligation under the swap agreement decreased by $528,000 which was recorded as a reduction of interest expense. Excluding the non-cash charges related to early extinguishment of debt in 2002 and the change in the market value of the interest rate swap agreement, interest expense actually increased by $0.8 million from 2002 to 2003. Such increase resulted from our increased average debt balance as a result of funding our acquisitions of ABI and the rapid diagnostic product lines from Abbott, but partially offset by lower average interest rates in 2003.

On February 10, 2004, we completed a sale of $150 million of 8.75% senior subordinated notes due 2012 in a private placement to qualified institutional buyers. Of the proceeds, we used $125 million to pay down our term loans and revolving credit facility under our senior credit facility and $9 million to pay down our 9% subordinated notes. We retained the remaining proceeds, net of fees and expenses related to the transaction, for general corporate purposes. As a result of the prepayment of outstanding balances under our senior credit facility and the 9% subordinated notes, we will record a write-off of deferred financing costs and prepayment fees and penalties related to the prepayment of the debt aggregating $3.5 million in the first quarter of 2004. These charges will be recorded to interest expense. In addition, because the senior subordinated notes accrue interest at a higher rate than the borrowings under our senior credit facility, we expect interest expense to increase in 2004.

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

(in thousands)	2003	2002 (restated)
Interest income	$ 1,043	$ 1,423
Foreign exchange gains and (losses), net	5	(1,618)
Other	5,393	9,309
Total other income (expense), net	$ 6,441	$ 9,114

Interest income decreased by $380,000, or 27%, to $1.0 million in 2003 from $1.4 million in 2002. The decrease in interest income resulted from our lower average cash balance during 2003, as we had used a significant portion of our cash to help finance our acquisitions.

A significant portion of other income (expense), net, generally represents foreign currency exchange gains and losses. In 2003, we recognized foreign exchange gains of $5,000 compared to losses of $1.6 million in 2002. The significant foreign exchange loss in 2002 resulted from the weakened U.S. Dollar against the Japanese Yen and Euro, as one of our bank loans, which was prepaid in November 2002, was denominated in Japanese Yen and certain receivables of our Irish subsidiary are denominated in U.S. Dollar while its functional currency is the Euro, respectively.

Further, included in other income (expense), net, in 2003 was an aggregate of $1.3 million of past royalties awarded to us as part of several patent infringement settlements and a one-time gain of $3.8 million recorded in connection with an agreement with Unilever which resolved certain issues that arose out of our acquisition of the Unipath business. In addition, other income (expense), net, in 2003 included a gain for the recovery of legal costs of $187,000 as noted above in our discussion of general and administrative expense. Included in other income (expense), net, in 2002 was a one-time non-cash gain of $9.6 million which resulted from the repurchase of the beneficial conversion feature associated with the early extinguishment of an issue of $20 million in subordinated promissory notes in March 2002.

Provision for Income Tax. Provision for income taxes decreased by $1.5 million, or 56%, to $1.2 million in 2003 from $2.7 million in 2002. The effective tax rate was 9% in 2003 compared to 14% in 2002. The significant decrease in the effective tax rate from 2002 to 2003 related to the recognition and benefit of certain deferred tax assets. In 2003, we recognized $440,000 of benefit from the reduction of the valuation allowance on the net operating loss, or NOL, carry-forward of our Irish subsidiary due to our assessment that we would more likely than not realize the benefit of this NOL. In addition, we recognized $780,000 of tax benefit in the United Kingdom for the enhanced deduction for research and development activity at our Unipath operations. Lastly, as a result of certain favorable developments with foreign tax authorities in the fourth quarter of 2003, we recognized $645,000 of tax benefit in the United Kingdom from the use of interest expense to offset operating profits at our Unipath operations, which we had previously not benefited from. Of the 2003 provision for income taxes, $860,000 related to the Unipath business. The remaining businesses recorded state or local tax provisions totaling $340,000. We did not record any provision for U.S. federal income taxes because of the availability of NOL's and NOL carry-forwards. We currently anticipate our 2004 effective tax rate to be approximately 18%.

Income (Loss) from Continuing Operations. We generated income from continuing operations in 2003 of $12.3 million while in 2002 we generated a loss from continuing operations of $21.9 million. After taking into account charges for dividends, redemption premium and amortization of a beneficial conversion feature related to our Series A redeemable convertible preferred stock, we had income from

continuing operations available to common stockholders of $11.3 million and $11.5 million, or $0.72 and $0.64 per basic and diluted common share, respectively, in 2003 and a loss from continuing operations available to common stockholders of $33.8 million, or $3.40 per basic and diluted common share, in 2002. The addition of Wampole in September 2002 and the rapid diagnostic products from Abbott in September 2003 contributed an incremental income of $2.8 million and $4.1 million, respectively, in 2003 compared to 2002. The remaining income in 2003 and the significant losses in 2002 resulted predominantly from various non-cash, nonrecurring and/or infrequent gains and charges recorded in the respective years as described above and in the following section titled "*Year Ended December 31, 2002 Compared to Year Ended December 31, 2001*." See note 11 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for the calculation of earnings per share.

EBITDA. EBITDA represents income (loss) from continuing operations before interest, income taxes, depreciation and amortization. We generated EBITDA in 2003 of $37.7 million while in 2002 we generated EBITDA of $4.8 million. The fluctuation in EBITDA from 2002 to 2003 partially resulted from the addition of Wampole in September 2002 and the rapid diagnostic products from Abbott in September 2003, which contributed an incremental EBITDA of $6.4 million and $4.3 million, respectively, in 2003 compared to 2002. The remaining increase in EBITDA from 2002 to 2003 resulted from various non-cash, nonrecurring and/or infrequent gains and charges recorded in the respectively years as described above and in the following section titled "*Year Ended December 31, 2002 Compared to Year Ended December 31, 2001*", excluding depreciation and amortization of $15.6 million and $10.3 million in 2003 and 2002, respectively. See footnote 3 to the selected consolidated financial data table included under Item 6 of this Annual Report on Form 10-K for (i) a reconciliation of income (loss) from continuing operations to EBITDA and (ii) the reasons why our management believes that the presentation of EBITDA provides useful information to investors regarding our financial condition and results of operations.

Cumulative Effect of a Change in Accounting Principle. On January 1, 2002, we adopted Statement of Financial Accounting Standards, or SFAS, No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 142 requires annual impairment tests to be performed on all reporting units, as defined in the statement, with carrying values for goodwill. 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 on January 1, 2002. This impairment charge was recorded as a cumulative effect of a change in accounting principle. There were no charges due to a change in accounting principle during 2003.

Net Income (Loss). We generated net income in 2003 of $12.3 million while in 2002 we generated a net loss of $34.0 million. After taking into account charges for dividends, redemption premium and amortization of a beneficial conversion feature related to our Series A redeemable convertible preferred stock, we had net income available to common stockholders of $11.3 million and $11.5 million, or $0.72 and $0.64 per basic and diluted common share, respectively, in 2003 and a loss available to common stockholders of $46.0 million, or $4.62 per basic and diluted common share, in 2002. The addition of Wampole in September 2002 and the rapid diagnostic products from Abbott in September 2003 contributed an incremental income of $2.8 million and $4.1 million, respectively, in 2003 compared to 2002. The remaining income in 2003 and the significant losses in 2002 resulted predominantly from various non-cash, nonrecurring and/or infrequent gains and charges as described above and in the following section titled "*Year Ended December 31, 2002 Compared to Year Ended December 31, 2001*." See note 11 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for the calculation of earnings per share.

Year Ended December 31, 2002 Compared to Year Ended December 31, 2001

Net Product Sales. Net product sales increased by $153.1 million, or 324%, to $200.4 million in 2002 from $47.3 million in 2001. The significant increase resulted predominantly from our acquisitions of the Unipath business, IMN and Wampole. The Unipath business, which primarily includes our Clearblue products, contributed $88.4 million to our growth in net product sales, as it generated net product sales of $90.5 million in 2002, compared to only $2.2 million in 2001 (because it was acquired late 2001). IMN and Wampole contributed $43.4 million and $12.5 million, respectively, to our growth of net product sales in 2002 since their respective acquisition dates. Our business units that existed prior to these acquisitions also contributed $4.8 million of the growth in net product sales in 2002, or a 11% growth from their 2001 net product sales, which primarily resulted from an increase in sales volume in private label home pregnancy detection and ovulation prediction tests and a change in product sales mix, as well as increased advertising efforts relating to our nutritional supplements. Additionally, our subsidiary in Ireland contributed a one-time $4.0 million net product sales increase during 2002 through its diabetes-related packaging contract with a subsidiary of Johnson & Johnson. This packaging contract, which generated net product sales of $5.1 million in 2002 and $1.1 million in 2001, was a transitional service arrangement arising out of the November 21, 2001 split-off and merger transaction, in which Johnson & Johnson acquired IMT. The transitional service arrangement, together with the revenue generated therefrom, terminated in August 2002.

Net Product Sales by Business Segment. Net product sales by business segment for 2002 and 2001 are as follows:

	2002	2001	% Increase
(in thousands)	**(restated)**		
Consumer products	$ 167,359	$ 36,677	356%
Professional diagnostic products	33,040	10,591	212%
Total net product sales	$ 200,399	$ 47,268	324%

The growth in net product sales from our consumer products was primarily the result of our acquisitions of the Unipath business and IMN. The increase in net product sales from our professional diagnostic products was primarily the result of our acquisitions of the Unipath business and Wampole.

Net Product Sales by Geographic Location. Net product sales by geographic location for 2002 and 2001 are as follows:

	2002	2001	% Increase
(in thousands)	**(restated)**		
United States	$ 106,821	$ 33,269	221%
Europe	67,863	6,800	898%
Other	25,715	7,199	257%
Total net product sales	$ 200,399	$ 47,268	324%

The increase in net product sales in the United States primarily resulted from the addition of the Clearblue products from the Unipath business, the Wampole products and the IMN products and the increased sales of private label home pregnancy detection and ovulation prediction tests. The increase in net product sales in Europe and other countries resulted from our acquisition of the Unipath business.

License Revenue. During 2002, we collected $6.4 million in license and royalty fees, of which $6.2 million, or 96%, was generated from the license agreements acquired as part of our acquisition of the Unipath business. We also acquired certain revenue generating license agreements as part of our

acquisition of Wampole, which license agreements contributed $227,000, or 4%, of our license revenue in 2002. Until we acquired the Unipath business in late 2001, we did not hold license and royalty revenue generating agreements. Therefore, we did not collect any such revenue in 2001.

Gross Profit from Net Product Sales. Gross profit from net product sales increased by $68.0 million, or 330%, to $88.6 million in 2002 from $20.6 million in 2001. Total gross margin from net product sales was 44% in both 2002 and 2001. Consistent with the growth in net product sales, the increase in gross profit was primarily due to our acquisitions of the Unipath business, IMN and Wampole, which contributed increases of gross profit from net product sales of $52.3 million, $4.5 million and $4.9 million, respectively, in 2002. Sales of our private label home pregnancy detection and ovulation prediction tests contributed $3.2 million to the increase in gross profit from net product sales as a result of volume-related sales growth and manufacturing efficiencies. Our branded nutritional supplements net product sales increase, together with reduced returns as a result of the change in product mix, contributed $3.2 million of the increase in gross profit from net product sales.

Gross Profit from Net Product Sales by Business Segment. Gross profit from net product sales by business segment for 2002 and 2001 are as follows:

(in thousands)	2002 (restated)	2001	% Increase
Consumer products	$ 72,961	$ 14,999	386%
Professional diagnostic products	15,688	5,607	180%
Total gross profit from net product sales	$ 88,649	$ 20,606	330%

Gross margin from our consumer product sales was 44% in 2002, compared to 41% in 2001. The increase in gross margin from our consumer product sales primarily resulted from the addition of the consumer diagnostic products we obtained in connection with our acquisition of the Unipath business. Gross margin from our professional diagnostic product sales was 47% in 2002, compared to 53% in 2001, which decrease resulted from the change in the product mix.

Purchased In-Process Research and Development. In the fourth quarter of 2001, we recorded a $7.0 million non-cash charge for an in-process research and development project, or IPRD Project, that we acquired as part of the Unipath business. At the time of the acquisition, the research and development staff of the Unipath business was seeking to develop a digital-based technology. However, the technology being sought under this specific IPRD Project had not yet reached technological feasibility and had no alternative future use at the date of acquisition, and therefore, the portion of the purchase price allocated to this IPRD Project, or $7.0 million, was charged to expense on the acquisition date. The amount of the purchase price allocated to this IPRD Project represented the estimated fair value of the project determined using the income approach, whereby projected future cash flows were discounted to value the technology. An estimated royalty rate of 4% was applied to projected revenues to calculate pretax royalty savings attributed to completed technology. A 30% tax rate was used and then a risk-adjusted discount rate of 24% was applied. At the time of the Unipath business acquisition, we believed that many of the complex technical issues have been resolved; however, we had not obtained FDA approval of this technology. Therefore, the risk of not achieving commercialization was not only a developmental risk, but a regulatory risk as well. The work of a full project, which included demonstrating feasibility, defining the project, design, development, verification and clinical testing, and regulatory submission and approval, would need to be completed prior to a launch of a product based on this technology. In the second quarter of 2003, as we had initially anticipated, we obtained FDA clearance to market and sell our pregnancy test that uses the digital-based technology. We did not record any in-process research and development charges in 2002.

Research and Development Expense. Research and development expense increased by $12.7 million, or 706%, to $14.5 million in 2002 from $1.8 million in 2001. The increase resulted predominantly from our decision to invest extensively in research and development of new products and to improve upon our existing products, as evidenced by our acquisition of the Unipath business, pursuant to which we acquired a large research and development center located in Unipath's facility in Bedford, England. Prior to the acquisition of the Unipath business, our research and development expense was mostly related to the development of professional diagnostic products by our subsidiary in Israel.

Sales and Marketing Expense. Sales and marketing expense increased by $31.5 million, or 394%, to $39.5 million in 2002 from $8.0 million in 2001. Of this increase, $25.4 million resulted from the addition of the Unipath business. The IMN and Wampole acquisitions accounted for $2.1 million and $1.9 million, respectively, of the increase in sales and marketing expense from 2001 to 2002. The remaining increase in sales and marketing expense resulted primarily from our new radio advertising efforts in 2002 in an attempt to boost our nutritional supplement product sales. Sales and marketing expense as a percentage of net product sales increased to 20% in 2002 from 17% in 2001.

General and Administrative Expense. General and administrative expense increased by $16.4 million, or 140%, to $28.1 million in 2002 from $11.7 million in 2001. General and administrative expense as a percentage of net product sales decreased to 14% in 2002, compared to 25% in 2001. The addition of the Unipath business accounted for $12.7 million of the increase in general and administrative expenses in 2002. The IMN and Wampole acquisitions accounted for $2.4 million and $847,000, respectively, of the increase in general and administrative expenses in 2002. The remaining increase in general and administrative expense primarily resulted from increased legal fees for our defenses in certain litigation matters, some of which were inactive during 2001 and others were acquired through our business combinations or initiated by us in 2002.

Charge Related to Asset Impairment. In the first quarter of 2002, we recorded a non-cash 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 that we acquired 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 also note 5 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. No impairment charge was recorded during 2001.

Stock-Based Compensation Expense. Stock-based compensation expense was $10.6 million in 2002 and $10.4 million in 2001. The majority of the 2002 expense relates to a sale of our company's restricted stock made to our chief executive officer in 2001. At the time of the sale in 2001, we recorded a non-cash deferred compensation expense of $10.6 million because the purchase price of the stock was below its market value on the measurement date of the transaction. This deferred compensation expense was originally set to amortize over the vesting period of the restricted stock, and accordingly, we recorded compensation expense of $451,000 in 2001. However, due to an amendment in the terms of the restricted stock agreement in February 2002, we fully recognized the remaining unamortized deferred compensation expense, or $10.1 million, at that time. See note 12(c) of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Additionally, this amendment resulted in a new measurement date for this security. In the event that the employee ceases employment with our company prior to the full vesting of this security, additional compensation expense will be recorded. Also during 2001, we recorded a $9.3 million non-cash stock-based compensation expense, which represents the difference between the market value and exercise price of certain stock option grants to executive officers on the measurement date. See note 12(c) of our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The remaining stock-based compensation expense in both 2002 and 2001 primarily represents the fair

value of options and warrants to acquire our company's common stock that were issued to non-employees.

Interest Expense. Interest expense increased by $12.8 million, or 557%, to $15.1 million in 2002 from $2.3 million in 2001. The increase in interest expense in 2002 resulted from two debt financings, which aggregated $82.5 million and $35.0 million, which we conducted to fund the acquisitions of the Unipath business and Wampole, respectively. We also obtained additional financing in the aggregate amount of $53.0 million in November 2002, a significant portion of which we used to refinance the debt issued in connection with the acquisition of the Unipath business. In March and November of 2002, we recorded an aggregate of $4.5 million in amortization of deferred financing costs, non-cash original issue discounts and discounts in the form of a beneficial conversion feature related to the early extinguishment of certain subordinated promissory notes and bank debt. In addition, during 2002, we recorded a non-cash charge of $1.2 million to mark to market an interest rate swap agreement because the swap agreement did not qualify as a hedge for accounting purposes. See notes 6 and 9 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

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

	2002	2001
(in thousands)	**(restated)**	
Interest income	$ 1,423	$ 385
Foreign exchange gains and (losses), net	(1,618)	(727)
Other	9,309	(1,674)
Total other income (expense), net	$ 9,114	$ (2,016)

Interest income increased by $1.0 million, or 264%, to $1.4 million in 2002 from $385,000 in 2001. The increase in interest income resulted from higher average cash balances during a portion of 2002 due to a follow-on public offering of 1.6 million shares of our common stock at $23 per share in May 2002 and a $41.4 million capitalization by our former parent, IMT, during our split-off from IMT in November 2001. During 2002, we incurred foreign exchange losses of $1.6 million, compared to losses of $727,000 during 2001. The increase in foreign exchange transaction losses in 2002 resulted from the weakened U.S. Dollar versus the Japanese Yen and Euro as one of our bank loans, which was prepaid in November 2002, was denominated in Japanese Yen and certain receivables of our Irish subsidiary are denominated in the U.S. Dollar while its functional currency is the Euro, respectively. Also included in other income (expense), net, in 2002 is a one-time non-cash gain of $9.6 million which resulted from the repurchase of the beneficial conversion feature associated with the early extinguishment of an issue of $20.0 million in subordinated promissory notes in March 2002 and a litigation settlement charge of $218,000. During 2001, we also recorded a litigation settlement charge of $1.7 million which is included in other income (expense), net.

Provision for Income Taxes. Provision for income taxes increased by $549,000, or 26%, to $2.7 million in 2002 from $2.1 million in 2001. Of the 2002 provision for income taxes, $2.4 million related to the Unipath business. The remaining businesses recorded local tax provisions totaling only $309,000 in 2002 because of the availability of net operating losses, or NOL, and NOL carryforwards. Included in the 2001 provision for income taxes was a charge of $1.3 million to write-off certain deferred tax assets which we did not believe would provide us with future tax benefits as a result of the split-off from IMT in November 2001. See note 14 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

Income (Loss) from Continuing Operations. In 2002, we generated a loss from continuing operations of $21.9 million. After taking into account charges for dividends, redemption premium and

amortization of discounts in the form of beneficial conversion feature with respect to our Series A redeemable convertible preferred stock, we had a loss from continuing operations available to common stockholders of $33.8 million, or $3.40 per basic and diluted share, in 2002. In 2001, we generated a loss from continuing operations of $24.8 million, or $3.89 per basic and diluted share. The losses in 2002 and 2001 resulted from various factors as described above.

EBITDA. EBITDA represents income (loss) from continuing operations before interest, income taxes, depreciation and amortization. We generated EBITDA in 2002 of $4.8 million while in 2001 we generated EBITDA of $(17.5) million. Most significantly, the increase in EBITDA from 2001 to 2002 resulted from the addition of the Unipath business in December 2001, which contributed an incremental EBITDA of $13.3 million in 2002 compared to 2001. The remaining fluctuation in EBITDA from 2001 to 2002 resulted from various factors as described above, excluding depreciation and amortization of $10.3 million and $3.2 million in 2002 and 2001, respectively. See footnote 3 to the selected consolidated financial data table included under Item 6 of this Annual Report on Form 10-K for (i) a reconciliation of income (loss) from continuing operations to EBITDA and (ii) the reasons why our management believes that the presentation of EBITDA provides useful information to investors regarding our financial condition and results of operations.

Cumulative Effect of a Change in Accounting Principle. On January 1, 2002, we adopted Statement of Financial Accounting Standard, or SFAS, No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 142 requires annual impairment tests to be performed on all reporting units, as defined in the statement, with values recorded for goodwill. 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 on January 1, 2002. This impairment charge was recorded as a cumulative effect of a change in accounting principle. See note 5 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. There were no charges due to a change in accounting principle in 2001.

Net Income (Loss). We generated a net loss of $34.0 million in 2002. After taking into account charges for dividends, redemption premium and amortization of discounts in the form of beneficial conversion feature with respect to our Series A redeemable convertible preferred stock, we had a net loss available to common stockholders of $46.0 million, or $4.62 per basic and diluted share, in 2002. The net loss in 2002 resulted from various factors as described above. In 2001, we generated a net loss of $24.7 million, or $3.88 per basic and diluted share. In 2001, there were no dividends or discounts that would have reduced net loss available to common stockholders. See notes 1, 2(k) and 11 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for the calculation of earnings per share.

Supplementary Quarterly Financial Information

As discussed on page 25 of Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" and note 2(q) of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we restated our previously issued consolidated financial statements as of and for the year ended December 31, 2002 to reverse a realized foreign exchange gain of $2.6 million related to the repayment of a portion of a long-term intercompany loan that had previously been reported in interest expense and other expenses, net, and to instead reflect the change in value of the intercompany loan prior to repayment as a component of accumulated other comprehensive income. In connection with this restatement, we also restated our previously issued consolidated financial statements for the quarterly impacts of certain adjustments related to sales cut-off and sales incentive allowances, the effects of which on operating results had previously been corrected in the periods in which they had been identified rather than in the periods to which they related.

The restatements discussed above affected the first quarter of 2003 and the four quarters of 2002. The following presents selected quarterly financial data for each of the quarters in the years ended December 31, 2003 and 2002 with comparisons of restated amounts to previously reported amounts, where applicable.

(in thousands, except per share data)

	2003				
	First Quarter		Second Quarter(2)	Third Quarter(3)	Fourth Quarter(4)
	As Restated	As Reported			
Net revenue	$ 65,102	$ 64,807	$ 65,717	$ 72,393	$ 93,500
Gross profit	29,830	29,535	28,674	31,491	38,597
Income (loss) before accounting change	2,293	1,998	5,602	1,662	2,712
Net income (loss)	2,293	1,998	5,602	1,662	2,712
Income (loss) before accounting change available to common stockholders(1):					
Basic	2,120	1,824	5,461	1,519	2,212
Diluted	2,164	1,824	5,610	1,519	2,212
Income (loss) per common share before accounting change(1):					
Basic	$ 0.15	$ 0.13	$ 0.39	$ 0.09	$ 0.12
Diluted	$ 0.14	$ 0.12	$ 0.34	$ 0.08	$ 0.11

	2002							
	First Quarter(5)		Second Quarter(6)		Third Quarter		Fourth Quarter(7)	
	As Restated	As Reported	As Restated	As Reported	As Restated	As Reported	As Restated	As Reported
Net revenue	$ 36,025	$ 37,248	$ 51,735	$ 51,712	$ 53,522	$ 53,947	$ 65,522	$ 65,139
Gross profit	18,275	18,820	20,923	20,609	23,317	23,792	29,636	29,225
Interest and other income (expense), net	4,786	4,786	(3,044)	(3,044)	(2,159)	(2,159)	(5,538)	(2,945)
Income (loss) before accounting change	(19,854)	(19,309)	(2,374)	(2,688)	666	1,141	(313)	1,869
Net income (loss)	(32,002)	(31,457)	(2,374)	(2,688)	666	1,141	(313)	1,869
Income (loss) before accounting change available to common stockholders(1):								
Basic	(21,383)	(20,838)	(4,647)	(4,961)	(7,200)	(6,725)	(593)	1,589
Diluted	(21,383)	(20,838)	(4,647)	(4,961)	(7,200)	(6,725)	(593)	1,589
Income (loss) per common share before accounting change(1):								
Basic	$ (3.02)	$ (2.94)	$ (0.55)	$ (0.58)	$ (0.70)	$ (0.65)	$ (0.04)	$ 0.12
Diluted	$ (3.02)	$ (2.94)	$ (0.55)	$ (0.58)	$ (0.70)	$ (0.65)	$ (0.04)	$ 0.11

(1) Income (loss) before accounting change available to common stockholders and basic and diluted income (loss) per share are computed as consistent with the annual per share calculations described in notes 1, 2(k) and 11 of our consolidated financial statements included elsewhere in this Annual

Report on Form 10-K.

(2) Included in income before accounting change and net income in the second quarter of 2003 is a one-time gain of $3.8 million recorded in connection with an agreement with Unilever which resolved certain issues that arose out of our acquisition of the Unipath business.

(3) Included in income before accounting change and net income in the third quarter of 2003 is a one-time gain of $741,000 as a result of insurance recovery of legal costs previously incurred.

(4) Included in income before accounting change and net income in the fourth quarter of 2003 are (i) reversals of allowances for returns and trade spending of specific products aggregating $905,000, which were established in prior years and were deemed no longer needed based upon current business trends, and (ii) tax benefits aggregating $1.2 million, which resulted from the reduction of the valuation allowance on the NOL carryforward of our Irish subsidiary due to our assessment that we would more likely than not realize the benefit of this NOL and for the enhanced deduction for research and development activity at our Unipath operations in the United Kingdom.

(5) Included in the loss before accounting change in the first quarter of 2002 are (i) an impairment charge of $12.7 million representing a write-off of certain intangible assets, (ii) a non-cash stock-based compensation charge of $10.1 million relating to a restricted stock award made in 2001, the terms of which were amended in 2002, and (iii) a gain of $9.6 million related to the early extinguishment of certain subordinated promissory notes and the related repurchase of the beneficial conversion feature associated with these subordinated promissory notes, which was included as a component of other income, net, in the consolidated statement of operations included elsewhere in this Annual Report on Form 10-K. Net loss for the first quarter of 2002 also includes a $12.1 million charge for the cumulative effect of an accounting change.

(6) The second quarter of 2002 includes a $217,000 charge for a litigation settlement.

(7) Included in loss before accounting change and net loss in the fourth quarter of 2002 is interest expense of $3.2 million related to an early extinguishment of debt.

Liquidity and Capital Resources

Based upon our current working capital position, current and long-term operating plans and expected business conditions, we believe that our existing capital resources and credit facilities will be adequate to fund our operations, including our outstanding debt and other commitments, as discussed below, for the next 12 months and the foreseeable future. This may be adversely impacted by unexpected costs associated with defending our existing lawsuits and/or unforeseen lawsuits against us and integrating the operations of Ostex and ABI and the product lines acquired from Abbott Laboratories. We also cannot be certain that our underlying assumed levels of revenues and expenses will be realized. In addition, we intend to continue to make significant investments in our research and development efforts related to the substantial intellectual property portfolio we now own, including the intellectual property acquired in connection with our acquisitions of Ostex and ABI and from Abbott Laboratories. We may also choose to further expand our research and development efforts and may pursue the acquisition of new products and technologies through licensing arrangements, business acquisitions, or otherwise. We may also choose to make significant investment to pursue legal remedies against potential infringers of our intellectual property. If we decide to engage in 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, may be available only on terms which could have a negative impact 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.

Changes in Cash Position

As of December 31, 2003, we had cash and cash equivalents of $24.6 million, a $6.0 million decrease, or 20%, from December 31, 2002. We have historically funded our business through operating cash flows, proceeds from borrowings and the issuance of equity securities, as well as contributions from our former parent prior to the split-off and merger transaction with Johnson & Johnson in November 2001. During 2003, we generated cash of $9.8 million from operating activities, which resulted from net income, adjusted for non-cash items, of $28.3 million, offset by a net working capital increase, excluding change in the cash balance, of $18.5 million. Our non-equity financing activities, primarily borrowings under our senior credit facility, net of scheduled principal repayments and

financing fees, provided us with cash of $66.0 million during 2003. In addition, we received $4.0 million in proceeds from the exercises of common stock options and warrants during 2003.

During 2003, we used cash of $89.1 million for our investing activities. Our investing activities consisted of $78.5 million paid for acquisitions of businesses and intellectual property and $11.1 million in capital expenditures, offset by $0.5 million related to a decrease in other non-current assets and proceeds received from the sale of property and equipment.

On February 10, 2004, we sold $150.0 million of 8 3/4% senior subordinated notes, or Bonds, due 2012 in a private placement to qualified institutional buyers. Net proceeds from this offering after underwriters' commissions and the prepayment of certain debt facilities and related financing fees and prepayment penalties, as discussed below, amounted to $11.4 million. We intend to use the net proceeds from the Bonds issuance for the payment of related offering expenses and general corporate purposes.

Investing Activities

On June 30, 2003, we acquired 100% of the outstanding common stock of Ostex through a merger transaction. The preliminary aggregate purchase price of Ostex was $33.4 million, which consisted of 1,596,821 shares of our company's common stock with an aggregate fair value of $23.5 million, the assumption of fully-vested stock options and warrants to purchase an aggregate of 303,000 shares of our company's common stock, which options and warrants have an aggregate fair value of $1.8 million, preliminary exit costs of $3.6 million (which includes severance, facility lease and exit costs, and disposal of assets), direct acquisition costs of $1.6 million and $2.9 million in assumed debt. We intend to exit the current facilities of Ostex in Seattle, Washington, and merge the operations into our other business units by mid-2004. Consequently, although we have a detailed exit plan and believe that our current estimated exit costs of $3.6 million are reasonable, actual spending for exit activities may differ from our current estimated total exit costs, which might impact the final aggregate purchase price.

On August 27, 2003, we acquired 100% of the outstanding common stock of ABI from Apogent. The preliminary aggregate purchase price of ABI was $28.8 million, which consisted of $13.4 million in cash, 692,506 shares of our common stock with an aggregate fair value of $14.3 million and preliminary direct acquisition costs of $1.1 million. We financed the cash portion of the purchase price by borrowing under our senior credit facility, as discussed below. The aggregate purchase price is preliminary as we are working to settle a working capital adjustment with Apogent under the purchase agreement and management is in the process of finalizing a restructuring plan for the operations of ABI, both of which could result in adjustments to the aggregate purchase price.

On September 30, 2003, we acquired from Abbott Laboratories certain assets related to Abbott's Fact plus line of consumer diagnostic pregnancy tests and the Abbott TestPack, Abbott TestPack plus and Signify lines of professional rapid diagnostics for various testing needs, including strep throat, pregnancy and drugs of abuse. The assets also included certain transferred and licensed intellectual property related to the products. The aggregate purchase price was $95.0 million, which consisted of $55.0 million in cash, $37.5 million in the form of 1,550,933 shares of our common stock, and direct acquisition costs of $2.5 million. We financed the cash portion of the purchase price by borrowings under our senior credit facility, as discussed below.

During 2003, we incurred $11.0 million in capital expenditures. A significant portion of our capital expenditure spending in 2003 was incurred to prepare our facilities for the manufacture of Pfizer's e.p.t products and to purchase equipment for the manufacture of an improved version of our traditional Clearblue pregnancy test. In addition, we made significant investments in laboratory instrument systems that we placed with our customers in connection with our national roll out of the AtheNa Multi-Lyte ANA Test System during 2003. To a lesser extent, capital expenditures in 2003 related to equipment purchased to support the manufacture of our new Clearblue Easy Digital pregnancy test. We also

purchased equipment to support our various research and development activities. We expect our 2004 capital expenditure spending to be at least equal to the level of the 2003 spending.

Financing Activities

On February 10, 2004, we completed the sale of $150.0 million of 8 3/4% Bonds due 2012 in a private placement to qualified institutional buyers. Net proceeds from this offering amounted to $145.9 million, which was net of underwriters' commissions of $4.1 million. Of the net proceeds, we used $125.3 million to repay all of our outstanding indebtedness and related financing fees under our primary senior credit facility and $9.2 million to prepay our outstanding 9% subordinated promissory notes and related prepayment penalties, as discussed below. The remaining $11.4 million of unused proceeds will be used for Bond offering expenses and general corporate purposes. We also retained the $50.0 million in available credit under our primary senior credit facility after our repayment of the outstanding borrowings using the Bond proceeds.

The Bonds accrue interest from the date of their issuance, or February 10, 2004, at the rate of 8.75% per year. Interest on the Bonds will be payable semi-annually in arrears on each February 15 and August 15, commencing on August 15, 2004. We may redeem the Bonds, in whole or in part, at any time on or after February 15, 2008, at a redemption price equal to 100% of the principal amount plus a premium declining ratably to par, plus accrued and unpaid interest. In addition, prior to February 15, 2007, we may redeem up to 35% of the aggregate principal amount of the Bonds issued with the proceeds of qualified equity offerings at a redemption price equal to 108.75% of the principal amount, plus accrued and unpaid interest. If we experience a change of control, we may be required to offer to purchase the Bonds at a purchase price equal to 101% of the principal amount, plus accrued and unpaid interest. We might not be able to pay the required price for Bonds presented to us at the time of a change of control because our primary senior credit facility or other indebtedness may prohibit payment or we might not have enough funds at that time.

The Bonds are unsecured and are subordinated in right of payment to all of our existing and future senior debt, including our guarantee of all borrowings under our primary senior credit facility. The Bonds are effectively subordinated to all existing and future liabilities, including trade payables, of those of our subsidiaries that do not guarantee the Bonds.

The Bonds are guaranteed by all of our domestic subsidiaries that are guarantors or borrowers under our primary senior credit facility, which excludes our subsidiary IMN in New Jersey. The guarantees are general unsecured obligations of the guarantors and are subordinated in right of payment to all existing and future senior debt of the applicable guarantors, which includes their guarantees of, and borrowings under our primary senior credit facility.

The indenture governing the Bonds contains covenants that will limit our ability and the ability of our subsidiaries to, among other things, incur additional indebtedness in the aggregate, subject to our interest coverage ratio, pay dividends or make other distributions or repurchase or redeem our stock, make investments, sell assets, incur liens, enter into agreements restricting our subsidiaries' ability to pay dividends, enter into transactions with affiliates and consolidate, merge or sell all or substantially all of our assets. These covenants are subject to certain exceptions and qualifications.

On November 14, 2002, our company and certain of our subsidiaries entered into our primary senior credit agreement with a group of banks for credit facilities in the aggregate amount of up to $55.0 million. On August 27, 2003, to finance the cash portion of our acquisition of ABI, we amended the senior credit agreement, whereby we increased our borrowing capacity under the senior credit facilities to $70.0 million. On September 30, 2003, to finance the cash portion of our acquisition of the rapid diagnostics product lines from Abbott Laboratories, we further amended the senior credit agreement, whereby the aggregate amount available under the senior credit facilities was further increased to $135.0 million. The amended senior credit agreement dated September 30, 2003 consisted of two U.S. term loans, Term Loan A for $35.1 million and Term Loan B for $40.0 million, a European

term loan for $9.9 million, a U.S. revolving line of credit of up to $25.0 million, and a European revolving line of credit of up to $25.0 million. Aggregate borrowings as of December 31, 2003 amounted to $84.9 million under the term loans and $39.9 million under the revolving lines of credit. The unused portion of the revolving lines of credit totaled $10.1 million as of December 31, 2003. As discussed above, we repaid all outstanding borrowings under our primary senior credit agreement with the proceeds from the Bonds issuance in February 2004 and we will retain the $50 million availability under the revolving lines of credit, subject to continuing covenant compliance.

We may repay any future borrowings under the revolving lines of credit at any time but in no event later than March 31, 2008. We are required to make mandatory prepayments under our primary senior credit facility if we meet certain cash flow thresholds, issue equity securities or subordinated debt, or sell assets not in the ordinary course of our business.

Borrowings under the revolving lines of credit bear interest at either (1) the London Interbank Offered Rate, or LIBOR, as defined in the credit agreement, plus applicable margins or, at our option, (2) a floating Index Rate, as defined in the credit agreement, plus applicable margins. Applicable margins if we choose to use the LIBOR or the Index Rate can range from 3.25% to 4.00% or 2.00% to 2.75%, respectively, depending on the quarterly adjustments that are based on our consolidated financial performance, commencing with the quarter ending March 31, 2004. As of December 31, 2003, the applicable interest rate under the revolving lines of credit, including the applicable margin, was 5.14%.

Borrowings under our primary senior credit facilities are secured by the stock of our U.S. and European subsidiaries, substantially all of our intellectual property rights and the assets of our businesses in the U.S. and Europe, excluding those assets of IMN, Orgenics Ltd., our Israeli subsidiary, and Unipath Scandinavia AB, our Swedish subsidiary, and the stock of IMN, Orgenics and certain smaller subsidiaries. Under the amended senior credit agreement, we must comply with various financial and non-financial covenants. The primary financial covenants pertain to, among other things, fixed charge coverage ratio, capital expenditures, various leverage ratios, earnings before interest, taxes and depreciation and amortization, or EBITDA, and a minimum cash requirement. Additionally, the amended senior credit agreement currently prohibits us from paying dividends. As of December 31, 2003, we were in compliance with the covenants.

On September 20, 2002, we sold units having an aggregate purchase price of $20.0 million to private investors to help finance our acquisition of Wampole. Each unit was issued for $50,000 and consisted of (1) a 10% subordinated promissory note in the principal amount of $50,000 and (2) a warrant to acquire 400 shares of our common stock at an exercise price of $13.54 per share. In the aggregate, we issued fully vested warrants to purchase 160,000 shares of our common stock, which may be exercised at any time on or prior to September 20, 2012. In addition, the placement agent for the offering of the units received a warrant to purchase 37,700 shares of our common stock, the terms of which are identical to the warrants sold as a part of the units. The 10% subordinated notes accrue interest on the outstanding principal amount at 10% per annum, which is payable quarterly in arrears on the first day of each calendar quarter starting October 1, 2002. The 10% subordinated notes mature on September 20, 2008, subject to acceleration in certain circumstances, and we may prepay the 10% subordinated notes at any time, subject to certain prepayment penalties. Subject to the consent of our senior lenders, we may repay the 10% subordinated notes and pay any prepayment penalty, in cash or in shares of our common stock valued at 95% of the average closing price of such stock over the ten consecutive trading days immediately preceding the payment date. The 10% subordinated notes are expressly subordinated to up to $150.0 million of indebtedness for borrowed money incurred or guaranteed by our company plus any other indebtedness that we incur to finance or refinance an acquisition. Among the purchasers of the units were three of our directors and officers and an entity controlled by our chief executive officer, who collectively purchased an aggregate of 37 units consisting of 10% subordinated notes in the aggregate principal amount of $1.85 million and warrants to purchase an aggregate of 14,800 shares of our common stock.

On September 20, 2002, also in connection with the financing of the Wampole acquisition, we sold 9% subordinated promissory notes in an aggregate principal amount of $9.0 million and 3% subordinated convertible promissory notes in an aggregate principal amount of $6.0 million to private investors for an aggregate purchase price of $15.0 million. The 9% subordinated notes and 3% convertible notes accrue interest on the outstanding principal amount at 9% and 3% per annum, respectively, which is payable quarterly in arrears on the first day of each calendar quarter starting October 1, 2002.

The 9% convertible notes were set to mature on September 20, 2008, subject to acceleration in certain circumstances, and we were allowed to prepay the outstanding principal balance at any time, subject to certain prepayment penalties and the consent of our senior lenders. In February 2004, we prepaid the outstanding balance of the 9% subordinated notes, or $9.0 million, and the consequential prepayment penalty of $180,000 with the proceeds from the Bond issuance in February 2004, as discussed above.

The 3% subordinated notes mature on September 20, 2008, subject to acceleration in certain circumstances. If we repay 3% convertible notes, we may do so in cash or in shares of our common stock valued at 95% of the average closing price of such stock over the ten consecutive trading days immediately preceding the payment date. At any time prior to the maturity date, the holders of the 3% convertible notes have the option to convert all of their outstanding principal amounts and unpaid interest into shares of our common stock at a conversion price equal to $17.45. Additionally, the outstanding principal amount and unpaid interest on the 3% convertible notes will automatically convert into common stock at a conversion price equal to $17.45 if, at any time after September 20, 2004, the average closing price of our common stock in any consecutive thirty day period is greater than $22.67. An entity controlled by our chief executive officer purchased 3% convertible notes in the aggregate principal amount of $3.0 million.

As of December 31, 2003, our subsidiary IMN had a total outstanding debt balance of $16.8 million, of which $13.1 million represented borrowings under a credit agreement with its senior lender and $3.7 million related to various notes payable and capital leases. Under the credit agreement with its senior lender, as amended, IMN can borrow up to $15.0 million under a revolving credit commitment and $4.2 million under a term loan commitment, subject to specified borrowing base limitations. Borrowings under the revolving credit commitment and the term loan bear interest at either 1.50% above the bank's prime rate or, at IMN's option, at 3.75% above the Adjusted Eurodollar Rate used by the bank. As of December 31, 2003, the interest rates on the loans with its senior lender ranged from 4.92% to 5.50%. The notes are collateralized by substantially all of IMN's assets. The credit agreement with its senior lender requires IMN to maintain minimum tangible net worth and contains various restrictions customary in such financial arrangements, including limitations on the payment of cash dividends. As of December 31, 2003, IMN was in compliance with such requirements and restrictions. The loans with its senior lender mature on October 15, 2004 and under the credit agreement, the loans are automatically extended for one year at each maturity date unless a ninety day termination notice is given in writing by either party to the agreement. IMN's other notes payable and capital leases mature on various dates through July 2008.

As of December 31, 2003, our subsidiary Orgenics had bank debt balances totaling $478,000. Orgenics' bank debt is collateralized by certain of Orgenics' assets. Orgenics' notes bear interest at rates ranging from 3.5% to 5.7% at December 31, 2003 and are payable on various dates through 2005.

As of December 31, 2003, there were 208,060 shares of our Series A redeemable convertible preferred stock, or Series A Preferred Stock, outstanding. The number of shares of common stock to be issued upon any voluntary conversion of one share of Series A Preferred Stock was equal to such number as was determined by dividing $30 by the conversion price in effect at the time of conversion. As of December 31, 2003, the conversion price was $15, subject to adjustment. Accordingly, each share of Series A Preferred Stock was convertible into two shares of common stock. Commencing on

December 20, 2003, we had the right to convert the Series A Preferred Stock into common stock in the event that the average closing price of our common stock exceeded $20 for any consecutive thirty trading day period ending not more than 10 days prior to the date of our mandatory conversion notice. Consequently, as of January 14, 2004, we converted all outstanding shares of the Series A Preferred Stock into shares of our common stock at a conversion rate of two shares of common stock per share of Series A Preferred Stock.

Each share of Series A Preferred Stock accrued dividends on a quarterly basis at $2.10 per annum, but only on those days when the closing price of our common stock was below $15. During 2003, we accrued $33,000 in dividends which were payable only if declared by the board of directors. No dividends were declared by the board of directors prior to the conversion of all outstanding shares of Series A Preferred Stock on January 14, 2004. In addition, our primary senior credit agreement would have prohibited us from paying dividends.

Income Taxes

As of December 31, 2003, we had approximately $73.8 million and $20.6 million of domestic and foreign net operating loss carryforwards, respectively, which either expire on various dates through 2023 or can be carried forward indefinitely. These losses are available to reduce federal and foreign taxable income, if any, in future years. These losses are also subject to review and possible adjustments by the applicable taxing authorities and may be limited in the event of certain cumulative changes in ownership interests of significant shareholders over a three-year period in excess of 50%. We have recorded a valuation allowance against a portion of the deferred tax assets related to our net operating losses and certain of our other deferred tax assets to reflect uncertainties that might affect the realization of such deferred tax assets, as these assets can only be realized via profitable operations. As of December 31, 2003, we determined that approximately $4.4 million of foreign net operating losses in Ireland were more likely than not to be realized due to recent and anticipated future profitable operations by our Irish subsidiary. Thus, we reduced the valuation allowance that was established against the deferred tax asset related to our net operating loss carryforwards in Ireland by $440,000 in 2003 to reflect this estimate.

Off-Balance Sheet Arrangements

We had no off-balance sheet arrangements as of December 31, 2003.

Contractual Obligations

The following table summarizes our principal contractual obligations as of December 31, 2003 and the effects such obligations are expected to have on our liquidity and cash flow in future periods.

	Payments Due by Period				
Contractual Obligations	**Total**	**2004**	**2005 - 2006**	**2007 - 2008**	**Thereafter**
			(in thousands)		
Long-term debt obligations(1)	$ 174,837	$ 14,055	$ 848	$ 26,100	$ 133,834
Capital lease obligations(2)	2,764	636	1,202	926	
Operating lease obligations(3)	66,247	6,422	10,520	8,944	40,361
Pension obligations	1,424	1,424			
Obligations under interest rate swap(4)	771	771			
Minimum royalty obligations	120	20	40	40	20
Purchase obligations(5)	15,600	15,600			
Total	$ 261,763	$ 38,928	$ 12,610	$ 36,010	$ 174,215

(1) See description of various financing arrangements in this section and note 6 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Included in the

payments obligation amount in 2004 is $13.1 million representing borrowings under IMN's senior credit agreement due to mature in October 2004. However, IMN's senior credit agreement renews automatically for one year at each maturity date unless a ninety day termination notice is given in writing by either party to the agreement.

(2) See note 7 to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

(3) See note 10(a) to our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

(4) Obligations under our interest rate swap agreement are calculated using current interest rates level.

(5) Purchase obligations include firm capital expenditure commitments and open purchase orders of other goods and services.

Critical Accounting Policies

The consolidated financial statements included elsewhere in this Annual Report on Form 10-K are prepared in accordance with accounting principles generally accepted in the United States of America. The accounting policies discussed below are considered by our management and our audit committee to be critical to an understanding of our financial statements because their application depends on management's judgment, with financial reporting results relying on estimates 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 our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K, include a comprehensive summary of the significant accounting policies and methods used in the preparation of our consolidated financial statements.

Revenue Recognition

We primarily recognize revenue when the following four basic criteria have been met: (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 generally do not enter into arrangements with multiple element deliverables. We recognize revenue upon title transfer of the products to third-party customers, 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.

We also receive license and royalty revenue from agreements with third-party 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 the licensees calculate based on their sales, which we have the right to audit under most of our agreements, are generally recognized upon receipt of the license or royalty payments unless we are able to reasonably estimate the fees as they are earned. License and royalty fees that are determinable prior to the receipt thereof are recognized in the period they are earned.

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

Sales arrangements with customers for our consumer products generally require us to accept product returns. From time to time, we also enter into sales incentive arrangements with our retail customers, which generally reduce the sale prices of our products. As a result, we must establish allowances for potential future product returns and claims resulting from our sales incentive arrangements against product revenue recognized in any reporting period. 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 total provision for sales returns and other allowances related to sales incentive arrangements amounted to approximately $46.2 million, $44.2 million and $4.8 million in 2003, 2002 and 2001, respectively, which had been recorded against product sales to derive our net product sales.

Similarly, our management must make estimates regarding uncollectible 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 and patterns. Our accounts receivable balance was $55.4 million and $36.9 million, net of allowances for doubtful accounts of $797,000 and $871,000, as of December 31, 2003 and 2002, respectively.

Valuation of Inventories

We state our inventories at the lower of the actual cost to purchase or manufacture the inventory or the estimated current market value of the inventory. In addition, we periodically review the inventory quantities on hand and record a provision for excess and obsolete inventory. This provision reduces the carrying value of our inventory and is calculated based primarily upon factors such as forecasts of our customers' demands, shelf lives of our products in inventory, loss of customers and manufacturing lead times. Evaluating these factors, particularly forecasting our customers' demands, requires management to make assumptions and estimates. Actual product sales may prove our forecasts to be inaccurate, in which case we may have underestimated or overestimated the provision required for excess and obsolete inventory. If, in future periods, our inventory is determined to be overvalued, we would be required to recognize the excess value as a charge to our cost of sales at the time of such determination. Likewise, if, in future periods, our inventory is determined to be undervalued, we would have over-reported our cost of sales, or understated our earnings, at the time we recorded the excess and obsolete provision. Our inventory balance was $47.0 million and $37.0 million, net of a provision for excess and obsolete inventory of $2.1 million and $1.3 million, as of December 31, 2003 and 2002, respectively.

Valuation of Goodwill and Other Long-Lived and Intangible Assets

Our long-lived assets include (1) property, plant and equipment, (2) goodwill and (3) other intangible assets. As of December 31, 2003, the balances of property, plant and equipment, goodwill and other intangible assets, net of accumulated depreciation and amortization, were $57.0 million, $233.8 million and $102.3 million, respectively.

Goodwill and other intangible assets are initially created as a result of business combinations or acquisitions of intellectual property. The values we record for goodwill and other intangible assets represent fair values calculated by independent third-party appraisers. Such valuations require us to provide significant estimates and assumptions which are derived from information obtained from the management of the acquired businesses and our business plans for the acquired businesses or

intellectual property. Critical estimates and assumptions used in the initial valuation of goodwill and other intangible assets include, but are not limited to: (i) future expected cash flows from product sales, customer contracts and acquired developed technologies and patents, (ii) expected costs to complete any in-process research and development projects and commercialize viable products and estimated cash flows from sales of such products, (iii) the acquired companies' brand awareness and market position, (iv) assumptions about the period of time over which we will continue to use the acquired brand, and (v) discount rates. These estimates and assumptions may be incomplete or inaccurate because unanticipated events and circumstances may occur. If estimates and assumptions used to initially value goodwill and intangible assets prove to be inaccurate, ongoing reviews of the carrying values of such goodwill and intangible assets, as discussed below, may indicate impairment which will require us to record an impairment charge in the period in which we identify the impairment.

Where we believe that property, plant and equipment and intangible assets have finite lives, we depreciate and amortize those assets over their estimated useful lives. For purposes of determining whether there are any impairment losses, as further discussed below, our management has historically examined the carrying value of our identifiable long-lived tangible and intangible assets and goodwill, including their useful lives where we believe such assets have finite lives, when indicators of impairment are present. In addition, SFAS No. 142 requires that impairment reviews be performed on the carrying values of all goodwill on at least 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, as compared to the carrying value of the asset, such loss would be charged to expense in the period we identify the impairment. Furthermore, if our review of the carrying values of the long-lived tangible and intangible assets with finite lives indicates impairment of such assets, we may determine that shorter estimated useful lives are more appropriate. In that event, we will be required to record additional depreciation and amortization in future periods, which will reduce our earnings.

Valuation of Goodwill

We have goodwill balances related to our consumer diagnostics and professional diagnostics reporting units, which amounted to $91.3 million and $142.5 million, respectively, as of December 31, 2003. As of December 31, 2003, we performed our annual impairment review on the carrying values of such goodwill using the discounted cash flows approach. Based upon this review, we do not believe that the goodwill related to our consumer diagnostics and professional diagnostics reporting units were impaired. Because future cash flows and operating results used in the impairment review are based on management's projections and assumptions, future events can cause such projections to differ from those used at December 31, 2003, which could lead to significant impairment charges of goodwill in the future. No events or circumstances have occurred since our review as of December 31, 2003, that would require us to reassess whether the carrying values of our goodwill have been impaired.

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 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 impairment review under SFAS No. 142. Although we believe that the carrying value of our long-lived tangible and intangible assets was realizable as of December 31, 2003, 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 through 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 $66.7 million as of December 31, 2003 due to uncertainties related to the future benefits, if any, from our deferred tax assets related primarily to our U.S. businesses and certain foreign net operating losses and tax credits. 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 or reduce our current 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 "Item 3. Legal Proceedings" in this Annual Report on Form 10-K. 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 and probable as the case progresses, in which case we will begin accruing for the expected loss.

In addition, in the section of this Annual Report on Form 10-K titled "Item 3. Legal Proceedings," 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 November 2002, the Emerging Issues Task Force, or EITF, reached consensus on Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. Revenue arrangements with multiple deliverables include arrangements which provide for the delivery or performance of multiple products, services and/or rights to use assets where performance may occur at different points in time or over different periods of time. EITF Issue No. 00-21 is effective for revenue arrangements entered into in

fiscal periods beginning after June 15, 2003. The adoption of the guidance under this consensus did not have an impact on our financial position, results of operations or cash flows.

In April 2003, the Financial Accounting Standards Board, or FASB, issued SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*, which amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities under SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*. In particular, SFAS No. 149 clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative discussed in SFAS No. 133, clarifies when a derivative contains a financing component, amends the definition of an underlying (as initially defined in SFAS No. 133) to conform it to language used in FASB Interpretation No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, and amends certain other existing pronouncements. SFAS No. 149 is effective for all contracts entered into or modified after June 30, 2003, subject to certain exceptions. The adoption of this statement did not have an impact on our financial position, results of operations, or cash flows.

In May 2003, the FASB issued SFAS No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, which establishes standards for how an issuer classifies and measures certain financial instruments with characteristics of both liabilities and equity. SFAS No. 150 requires that an issuer classify a financial instrument that is within its scope as a liability (or an asset in some circumstances), while many of such instruments were previously classified as equity or "mezzanine" equity. The statement also requires that income statement treatment be consistent with the balance sheet classification. That is, if the instrument is classified as a liability, payments to the holders are interest expense, not dividends, and changes in value are recorded in earnings. The statement relates to three specific categories of instruments: mandatorily redeemable shares, freestanding written put options and forward contracts that obligate an entity to purchase its own shares, and freestanding contracts that obligate an entity to pay with its own shares in amounts that are either unrelated, or inversely related, to the price of the shares. SFAS No. 150 is effective for financial instruments entered into or modified after May 31, 2003 and otherwise is effective in the first interim period beginning after June 15, 2003. The adoption of this statement did not have an impact on our financial position, results of operations, or cash flows.

In December 2003, the FASB issued a revision to FASB Interpretation, or FIN, No. 46, *Consolidation of Variable Interest Entities*. The revised FIN No. 46, which replaces the original FIN No. 46 issued in January 2003, clarifies the application of Accounting Research Bulletin No. 51, *Consolidated Financial Statements*, to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinated financial support. While this interpretation exempts certain entities from its requirements, it also expands the definition of a variable interest entity, or VIE, to a broader group of entities than those previously considered special-purpose entities, or SPE's, and specifies the criteria under which it is appropriate for an investor to consolidate VIE's. Application of the revised FIN No. 46 is required in financial statements of public entities that have interest in structures that are commonly referred to as SPE's for periods ending after December 15, 2003. For all other types of VIE's, application of the revised FIN No. 46 by public entities is required for periods ending after March 15, 2004. The application of this interpretation with respect to structures commonly referred to as SPE's did not have a material impact on our financial position, results of operations, or cash flows. We currently do not expect the application of this interpretation with respect to other types of VIE's to have a material impact on our financial position, results of operations, or cash flows.

In December 2003, the Securities and Exchange Commission, or SEC, published Staff Accounting Bulletin, or SAB, No. 104, *Revenue Recognition*. SAB No. 104 was effective upon issuance and

supersedes SAB No. 101, *Revenue Recognition in Financial Statements*, and rescinds the accounting guidance contained in SAB No. 101 related to multiple-element revenue arrangements that was superseded by EITF Issue No. 00-21. Accordingly, SAB No. 104 rescinds portions of the interpretive guidance included in Topic 13 of the codification of staff accounting bulletins. While the wording of SAB No. 104 has changed to reflect the guidance of EITF 00-21, the revenue recognition principles of SAB No. 101 have remained largely unchanged. The adoption of SAB No. 104 did not have a material effect on our financial position, results of operations, or cash flows.

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 carefully consider these factors with respect to 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 beginning on pages 2 and 65 of this report.

Our business has substantial indebtedness, which could have adverse consequences for us.

We currently have, and we will likely continue to have a substantial amount of indebtedness. As of February 29, 2004, we had approximately $192.1 million aggregate principal amount of indebtedness outstanding, of which $16.1 million is secured indebtedness, and $51.5 million of additional borrowing capacity under the revolving portions of our credit facilities. In addition, subject to restrictions in our credit facilities and the indenture governing the senior subordinated notes, we may incur additional indebtedness.

Our substantial indebtedness could affect our future operations in important ways. For example, it could:

make it more difficult to satisfy our obligations under the senior subordinated notes, our credit facilities and our other debt-related instruments;

require us 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;

limit our flexibility to adjust to market conditions, 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;

impair our ability to obtain additional financing;

place us at a competitive disadvantage compared to our competitors that have less debt; and

expose us to fluctuations in the interest rate environment with respect to our indebtedness that bears interest at variable rates.

We expect to obtain the money to pay our expenses and to pay the principal and interest on the senior subordinated notes, our senior credit facility and our other debt from cash flow from our operations and from additional loans under our senior credit facility, subject to continued covenant compliance. Our ability to meet our expenses thus depends on our future performance, which will be affected by financial, business, economic and other factors. We will not be able to control many of these factors, such as economic conditions in the markets in which we operate and pressure from

competitors. We cannot be certain that our cash flow will be sufficient to allow us to pay principal and interest on our debt and meet our other obligations. 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, including the notes, seek additional equity capital or borrow more money. We cannot guarantee that we will be able to do so on terms acceptable to us. In addition, the terms of existing or future debt agreements, including the credit agreement governing our senior credit facility and the indenture governing the senior subordinated notes, may restrict us from adopting any of these alternatives.

We have entered into agreements governing our indebtedness that subject us to various restrictions that may limit our ability to pursue business opportunities.

The agreements governing our indebtedness, including the credit agreement governing our senior credit facility and the indenture governing the senior subordinated notes, subject us to various restrictions on our ability to engage in certain activities, including, among other things, our ability to:

incur additional indebtedness;

pay dividends or make distributions or repurchase or redeem our stock;

acquire other businesses;

make investments;

make loans to or extend credit for the benefit of third parties or our subsidiaries;

enter into transactions with affiliates;

raise additional capital;

make capital or finance lease expenditures;

dispose of or encumber assets; and

consolidate, merge or sell all or substantially all of our assets.

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

Our credit facilities contain certain financial covenants 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 February 29, 2004, we had approximately $12.0 million of indebtedness outstanding under our various credit facilities and approximately $51.5 million of additional borrowing capacity under these credit facilities. The agreements governing these 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 fixed charge coverage, capital expenditures, various leverage ratios, minimum EBITDA, total net worth and minimum cash requirements. 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 payable, our lenders could proceed against any collateral securing such indebtedness, and our ability to borrow additional funds in the future may be limited.

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A default under any of our agreements governing our indebtedness could result in a default and acceleration of indebtedness under other agreements.

The agreements governing our indebtedness, including our senior credit facility and the indenture governing the senior subordinated notes, contain cross-default provisions whereby a default under one agreement could result in a default and acceleration of our repayment obligations under other agreements. If a cross-default were to occur, we may not be able to pay our debts or borrow sufficient funds to refinance them. Even if new financing were available, it may not be on commercially reasonable terms or terms that are acceptable to us. If some or all of our indebtedness is in default for any reason, our business, financial condition and results of operations could be materially and adversely affected.

We may not be able to satisfy our debt obligations upon a change of control.

Upon the occurrence of a "change of control," as defined in the indenture governing the senior subordinated notes, each holder of our senior subordinated notes will have the right to require us to purchase the notes at a price equal to 101% of the principal amount, together with any accrued and unpaid interest. Our failure to purchase, or give notice of purchase of, the senior subordinated notes would be a default under the indenture, which would in turn be a default under our senior credit facility. In addition, a change of control may constitute an event of default under our senior credit facility. A default under our senior credit facility would result in an event of default under our 3% convertible notes, 10% subordinated notes and, if the lenders accelerate the debt under our senior credit facility, the indenture, and may result in the acceleration of any of our other indebtedness outstanding at the time.

If a change of control occurs, we may not have enough assets to repay all of our indebtedness or to purchase all of the senior subordinated notes. Upon the occurrence of a change of control we could seek to refinance our existing indebtedness or obtain a waiver from the lenders or the holders of the senior subordinated notes. If we are not able to obtain a waiver or refinance our indebtedness on commercially reasonable terms, or at all, we may not be able to satisfy our obligations to holders of the senior subordinated notes upon a change of control.

Our acquisitions, and in particular our recent acquisitions of Ostex, ABI and the Abbott rapid diagnostics product lines, may not be profitable, and the integration of these businesses or product lines may be difficult and may lead to adverse effects.

Since we commenced activities in November 2001, we have acquired and attempted to integrate into our operations the Unipath business, IVC (now doing business as Inverness Medical Nutritionals Group, or IMN) and Wampole. On June 30, 2003, we acquired Ostex, on August 27, 2003, we acquired ABI, and on September 30, 2003, we acquired the Abbott rapid diagnostics product lines. The ultimate success of all of our acquisitions depends, in part, on our ability to realize the anticipated synergies, cost savings and growth opportunities from integrating these businesses or product lines into our existing businesses. However, the successful integration of independent companies or product lines is a complex, costly and time-consuming process. The difficulties of integrating companies and acquired assets include among others:

- consolidating manufacturing and research and development operations, where appropriate;
- integrating newly acquired businesses or product lines into a uniform financial reporting system;
- coordinating sales, distribution and marketing functions;
- establishing or expanding manufacturing, sales, distribution and marketing functions in order to accommodate newly acquired businesses or product lines;

preserving the important licensing, research and development, manufacturing and supply, distribution, marketing, customer and other relationships;

minimizing the diversion of management's attention from ongoing business concerns; and

coordinating geographically separate organizations.

We may not accomplish the integration of our acquisitions smoothly or successfully. The diversion of the attention of our management from our current operations to the integration effort and any difficulties encountered in combining operations could prevent us from realizing the full benefits anticipated to result from these acquisitions and adversely affect our other businesses. Ultimately, the value of any company, product line or assets that we have acquired may not be greater than or equal to their purchase prices.

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

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 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 synergies, cost savings or growth opportunities;

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:

issuances of dilutive 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 significant liabilities;

unfavorable financing terms;

large one-time expenses; and

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

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

If goodwill that we have recorded in connection with our acquisitions of other businesses becomes impaired, we could have to take significant charges against earnings.

In connection with the accounting for our acquisitions of the Unipath business, Wampole, Ostex, ABI and the Abbott rapid diagnostics product lines, we have recorded a significant amount of goodwill and other intangible assets. Under current accounting guidelines, 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.

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 multi-purpose facility that we currently use in Bedford, England.

One of our primary operating facilities is located in Bedford, England. The Bedford facility is a multi-purpose facility that is registered with the FDA, contains state-of-the-art research laboratories and is equipped with specialized manufacturing equipment. This facility currently provides the manufacturing for our Clearblue and Clearview products, serves as our primary research and development center and serves as the administrative center for our European operations. We also use this facility to manufacture the digital e.p.t pregnancy test for Pfizer, and we anticipate using this facility to manufacture the non-digital e.p.t pregnancy test for Pfizer in connection with our five-year supply arrangement with Pfizer for this product that begins in June 2004. We are currently using the Bedford facility pursuant to our acquisition agreement with Unilever relating to our acquisition of the Unipath business in late 2001. Unilever currently leases this facility from a third party landlord. Pursuant to the terms of Unilever's lease, Unilever cannot assign the lease or sublet the Bedford facility to us without first obtaining the landlord's consent. The landlord has not yet, and may not in the future, consent to an assignment of the lease or a sublease to us. The terms of our acquisition agreement obligate Unilever to provide to us the benefit of its lease of the Bedford facility. If Unilever is unable to successfully acquire such consent or otherwise enable us to realize the benefit of Unilever's lease of the Bedford facility, or if its lease is terminated, 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 increased production costs or manufacturing delays, which could prevent us from meeting contractual supply obligations or jeopardize important customer relationships. We may also suffer disruptions to our ongoing research and development while we are resolving these issues. We cannot assure you 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.

Manufacturing problems or delays could severely affect our business.

We produce most of our consumer products in our manufacturing facilities located in New Jersey, San Diego, Bedford, England and Galway, Ireland and some of our professional diagnostic tests in our manufacturing facilities located in Bedford, England, San Diego, Seattle and Yavne, Israel. Our production processes are complex and require specialized and expensive equipment. Replacement parts for our specialized equipment can be expensive and, in some cases, can require lead times of up to a year to acquire. In addition, our private label consumer products business, and our private label and bulk nutritional supplements business in particular, rely on operational efficiency to mass produce products at low margins per unit. We also rely on third parties to supply production materials and in some cases there may not be alternative sources immediately available.

In addition, we rely on third parties to manufacture most of our professional diagnostic products and certain components of our consumer diagnostic products, including products in development. For example, certain of the Abbott rapid diagnostics product lines are currently manufactured for us by Abbott Laboratories in Chicago under the terms of a transitional arrangement. Any event impacting our manufacturing facilities, our manufacturing systems or equipment, or our contract manufacturers or suppliers, including, without limitation, wars, terrorist activities, natural disasters and outbreaks of infectious disease (such as SARS), could delay or suspend shipments of products or the release of new products or could result in the delivery of inferior products. Our revenues from the affected products would decline or we could incur losses until such time as we were able to restore our production processes or 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.

We may not be successful in manufacturing, shipping and selling our new digital pregnancy test.

In the second quarter of 2003, we shipped the first orders for our new digital pregnancy test, Clearblue Easy Digital, which is the first consumer pregnancy test on the market to display test results in words. We also entered into a supply agreement with Pfizer pursuant to which we have agreed to supply Pfizer with a digital version of its e.p.t pregnancy tests on a non-exclusive basis, which began in December 2003. Instead of interpreting colored lines for a result, the digital display will spell out "Pregnant" or "Not Pregnant." Manufacturing or distribution problems, or other factors beyond our control, could negatively impact the effectiveness of these new products and prevent us from meeting customer demand or our own sales forecasts. In addition, we cannot assure you that the market will accept these new products or that any such acceptance will not dilute market acceptance of our other consumer pregnancy test products or the non-digital e.p.t pregnancy test, which we will manufacture for Pfizer for a period of five years beginning in June 2004. Accordingly, there is no assurance that these new products will increase our overall revenues or profitability.

We may experience difficulties that may delay or prevent our development, introduction or marketing of new or enhanced products.

We intend to continue to invest in product and technology development. The development of new or enhanced products is a complex and uncertain process. We may experience research and development, manufacturing, marketing and other difficulties that could delay or prevent our development, introduction or marketing of new products or enhancements. We can not be certain that:

- any of the products under development will prove to be effective in clinical trials;
- we will be able to obtain, in a timely manner or at all, regulatory approval to market any of our products that are in development or contemplated;
- any of such products can be manufactured at acceptable cost and with appropriate quality; or
- any such products, if and when approved, can be successfully marketed.

While we currently expect to launch a pro-thrombin test in late 2004, a congestive heart failure product in 2005 and new infectious disease products (including a high sensitivity strep throat test, rapid influenza A & B tests and a rapid HIV test) in 2004, the factors listed above, as well as manufacturing or distribution problems, or other factors beyond our control, could delay these launches. In addition, we cannot assure you that the market will accept these products. Accordingly, there is no assurance that our overall revenues will increase if and when these new products are launched.

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 and other foreign governments, as well as the FDA, and, to a lesser extent, the U.S. Drug Enforcement Administration, or the DEA, and local health agencies. These regulatory agencies may conduct periodic audits 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. These regulatory agencies may also impose new or enhanced standards that would increase our costs as well as the risks associated with non-compliance. For example, we anticipate that the FDA may soon finalize and implement "good manufacturing practice," or GMP, regulations for nutritional supplements. GMP regulations would require supplements to be prepared, packaged and held in compliance with certain rules, and might require quality control provisions similar to those in the GMP regulations for drugs. While our manufacturing facilities for nutritional supplements have been subjected to, and passed, third party inspections against anticipated GMP standards, the ongoing compliance required in the event that GMP regulations are adopted would involve additional costs and would present new risks associated with any failure to comply with the regulations in the future.

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 professional 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.

Our sales of branded nutritional supplements have been trending downward 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.

Our sales of branded nutritional products have declined each year since 1998 until the year 2002 when they increased slightly as compared to 2001. We believe that these products have under-performed because they are, for the most part, aging brands with limited brand recognition that face increasing private label competition. The overall 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. Though we did experience a slight increase in sales during 2002, the overall trend of declining sales for these products continued in 2003. More recently we have added new distribution of Posture D and entered into an agreement to serve as the exclusive U.S. distributor of Triomega. Otherwise, we do not expect significant sales growth of our existing branded nutritional products and we may experience further declines in overall sales of our branded nutritional products in the future.

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 tend to generate greater attention in the marketplace than do older products. 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 serve well-established market segments and, absent unforeseen new developments or trends, are not expected to benefit from rapid growth. A few of our vitamin and nutritional products 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 challenge the safety or effectiveness of these products could negatively impact the profitability of our vitamin and nutritional supplements business.

We market our Orgenics professional diagnostic products to small and medium sized customers in approximately 90 countries at considerable cost that reduces the operating margins for those products.

Because small and medium sized laboratories are the principal customers of our Orgenics professional diagnostic products, we sell these products worldwide in order to maintain sufficient sales volume. Our Orgenics professional diagnostic products are marketed in approximately 90 countries, including many third world and developing nations where smaller laboratories are the norm, more expensive technologies are not affordable and 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 professional diagnostics business. Our current material legal proceedings are:

- a counterclaim by Princeton BioMeditech Corporation, or PBM, against us in a patent infringement suit maintained by our subsidiaries, Inverness Medical Switzerland GmbH and Unipath Diagnostics, Inc., against PBM et. al. in which PBM alleges that we have breached various obligations to PBM arising out of its joint venture with us; and

- a suit brought by Quidel Corporation alleging that we are infringing U.S. Patent No. 4,943,522 and seeking a declaratory finding that Quidel does not infringe certain of our patents and certain other patents owned by co-defendant Armkel LLC and that the patents are invalid and/or unenforceable.

In connection with our split-off from IMT, we agreed to assume, to the extent permitted by law, and indemnify IMT for, all liabilities arising out of the women's health, nutritional supplements and professional 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, IMN, Wampole, Ostex and ABI, 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.

In October 2003, we met with the SEC regarding an informal inquiry concerning the resignation of our former independent accountants, Ernst & Young LLP, and certain accounting and financial matters that we discussed with the SEC in October 2003. On January 28, 2004, we received a request from the SEC for some additional factual information. We cannot predict what the outcome of this informal investigation will be.

In October 2003, in connection with an informal inquiry, we met with two representatives of the Boston office of the SEC's Division of Enforcement to respond to questions regarding Ernst & Young LLP's resignation and certain of the accounting and financial matters that we discussed with the SEC during the second quarter of 2003 after filing our Current Report on Form 8-K, event date April 11, 2003, to disclose Ernst & Young's resignation. We responded fully to the staff's requests for information. On January 28, 2004, in connection with its informal investigation, we received a request from the staff of the SEC for some additional factual information as a follow-up to our past response. We have fully responded to this request for additional information. We cannot predict whether the SEC will seek additional information or what the outcome of this informal investigation will be.

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. Customer concentration in these businesses is high, especially in our private label nutritional supplements business. In addition, customers of our branded and private label consumer products businesses purchase products through purchase orders only and are not obligated to make future purchases. We therefore rely on our ability to deliver quality products on time in order to retain and generate customers. If we fail to meet our customers' needs or expectations, whether due to manufacturing issues that affect quality or capacity issues that result in late shipments, we will harm our reputation and likely lose customers. The loss of a major customer and the failure to generate new accounts could significantly reduce our revenues or prevent us from achieving projected growth.

The profitability of our consumer products businesses may suffer if Pfizer Inc. is unable to successfully market and sell its e.p.t pregnancy tests.

Under the terms of a manufacturing, packaging and supply agreement that we entered into in June 2003 with Pfizer Inc., through one of its wholly-owned subsidiaries, Pfizer will purchase its non-digital e.p.t pregnancy tests from us beginning on June 6, 2004 and continuing until June 6, 2009. Additionally, under the terms of a separate supply agreement, in December 2003 we began supplying Pfizer with a digital version of its e.p.t pregnancy test on a non-exclusive basis. The amount of revenues or profits that we generate under these agreements will depend on the volume of orders that we receive from Pfizer. As a result, if Pfizer is unable to successfully market and sell its e.p.t pregnancy tests, or if other events adversely affect the volume of Pfizer's sales of its e.p.t pregnancy tests, then our future revenues and profit may be adversely affected.

Our private label nutritional supplements business is a low margin business susceptible to changes in costs and pricing pressures.

Our private label nutritional supplements business operates on low profit margins and we rely on our ability to efficiently mass produce nutritional supplements in order to make meaningful profits from this business. Changes in raw material or other manufacturing costs can drastically cut into or eliminate the profits generated from the sale of a particular product. For the most part, we do not have long-term supply contracts for our required raw materials and, as a result, our costs can increase with little notice. The private label nutritional supplements business is also highly competitive such that our ability to raise prices as a result of increased costs is limited. Customers generally purchase private

label products via purchase order, not through long-term contracts, and they often purchase these products from the lowest bidder on a product by product basis. The internet has enhanced price competition among private label manufacturers through the advent of on-line auctions, where customers will auction off the right to manufacture a particular product to the lowest bidder.

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

In recent years there has been a 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.

Approximately 36% of our net revenues were generated from outside the United States for the year ended December 31, 2003. A significant number of our employees, including manufacturing, sales, support and research and development personnel, are located in foreign countries, including England, Ireland and Israel. Conducting business outside of the United States subjects us to numerous risks, including:

- increased costs or reduced revenue as a result of movements in foreign currency exchange rates;
- 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;
- higher cost of sales resulting from import or export licensing requirements;
- lost revenues or other adverse affects as a result of economic or political instability in or affecting foreign countries in which we sell our products or operate; and
- adverse effects resulting from changes in foreign regulatory or other laws affecting the sales of our products or our foreign operations.

Because our business relies heavily on foreign operations and revenues, 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. Approximately 36% of our net revenues were generated from outside the United States during the year ended December 31, 2003. Our Clearblue pregnancy test product sales have historically been much stronger outside the United States, with 75% of net product sales of these products coming from outside the United States during the year ended December 31, 2003. In addition, the Abbott rapid diagnostics product lines, which were acquired on September 30, 2003, generate a majority of their profits from sales outside the United States. Furthermore, Persona is sold exclusively outside of the United States

and our Orgenics professional diagnostic products have always been sold exclusively outside of the United States. 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 subsidiaries. These exposures may change over time as business practices evolve and could result in increased costs or reduced revenue and could impact our 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, which develops, manufactures and sells certain of our professional 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's 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.

Terrorist attacks or acts of war may seriously harm our business.

Terrorist attacks or acts of war may cause damage or disruption to our company, our employees, our facilities and our customers, which could significantly impact our revenues, costs and expenses and financial condition. The terrorist attacks that took place in the United States on September 11, 2001 were unprecedented events that have created many economic and political uncertainties, some of which may materially adversely affect our business, results of operations and financial condition. The potential for future terrorist attacks, the national and international responses to terrorist attacks, and other acts of war, including the current conflict in Iraq, or hostility have created many economic and political uncertainties, which could materially adversely affect our business, results of operations, and financial condition in ways that we currently cannot predict.

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 professional 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 maintaining a competitive position in the development of products and technologies in our areas of focus. Our competitors may:

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

Also, the possibility of patent disputes with competitors holding foreign patent rights may limit or delay expansion possibilities for our diagnostics businesses 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, groceries 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 present and 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 parties may challenge patents or patent applications 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 patented, 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 professional diagnostic industries. We expect that our products and products in these industries could be increasingly 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 or require us to develop non-infringing technology, make substantial payments to third parties, or enter into royalty or license agreements, which may not be available on acceptable terms, or at all. If a successful claim of infringement was 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.

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. In addition, technology we own or license may have potential applications to this field and our research and development capabilities could be applied to this field. However, in conjunction with our split-off from IMT, we agreed not to compete with IMT and Johnson & Johnson in the field of diabetes for 10

years. In addition, Mr. Ron Zwanziger, our Chairman, Chief Executive Officer and President, and two of our senior scientists, Dr. David Scott and Dr. Jerry McAleer, have entered into consulting agreements with IMT that impose similar restrictions. Further, our license agreement with IMT 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.

We are obligated to indemnify IMT and others for liabilities and could be required to pay IMT and others 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.

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 professional diagnostics businesses.

While no claims for indemnification have yet been made, or may ever 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.

You are unlikely to be able to exercise effective remedies against Arthur Andersen LLP, our former independent public accountants.

Although we dismissed Arthur Andersen LLP as our independent public accountants in June 2002 and we now engage BDO Seidman, LLP, our consolidated financial statements as of December 31, 2001 and 2000 and for each of the three years in the period ended December 31, 2001, to the extent included in this report or previously filed reports or registration statements, were audited by Arthur Andersen.

On March 14, 2002, Arthur Andersen was indicted on federal obstruction of justice charges arising from the government's investigation of Enron Corporation. On June 15, 2002, a jury in Houston, Texas found Arthur Andersen guilty of these federal obstruction of justice charges. In light of the jury verdict and the underlying events, Arthur Andersen subsequently substantially discontinued operations and dismissed essentially its entire workforce. You are therefore unlikely to be able to exercise effective remedies or collect judgments against Arthur Andersen for any untrue statement of a material fact contained in the financial statements audited by Arthur Andersen or any omissions to state a material fact required to be stated in those financial statements.

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;

increased research and development expenses;

the timing of any future acquisitions;

general economic conditions; or

general stock market conditions or other economic or external factors.

Our historical financial information relating to periods beginning prior to our split-off from Inverness Medical Technology, Inc. on November 21, 2001 may not be representative of our results as a separate company.

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. The historical financial information relating to any periods beginning prior to November 21, 2001, included in our reports filed with the SEC, report on time periods prior to the split-off and reflect the operating history of our businesses when we 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 those periods. 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 have been made to produce these financial statements because IMT did not account for us as a single stand-alone business for those periods presented; and

the information, to the extent it does not report on a period ending on or after November 21, 2001, 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 the financial information for any periods beginning prior to November 21, 2001 may not appropriately reflect our operations during those periods as if we had operated as a stand-alone company.

Period-to-period comparisons of our operating results may not be meaningful due to our acquisitions.

We have engaged in a number of significant acquisitions in recent years which make it difficult to analyze our results and to compare them from period to period, including the acquisitions of the Unipath business in December 2001, IVC in March 2002, Wampole in September 2002, Ostex in June 2003, ABI in August 2003 and the Abbott rapid diagnostics product lines in September 2003. Period-to-period comparisons of our results of operations may not be meaningful due to these acquisitions and are not indications of our future performance. Any future acquisitions will also make our results difficult to compare from period to period in the future.

SPECIAL STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report 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 report. These differences may be the result of various factors, including those factors described in the "Certain Factors Affecting Future Results" section in this report and other risk factors identified from time to time in our periodic filings with the SEC. 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, including our ability to successfully maintain relationships with suppliers, or to put in place alternative suppliers on terms that are acceptable to us;

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, such as our recent acquisitions of Applied Biotech, Inc. and the Abbott rapid diagnostics product lines, and organizational restructurings consistent with our evolving business strategies;

our ability to satisfy the financial covenants and other conditions contained in the agreements governing our indebtedness;

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 SEC.

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 report 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 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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 eighteen months and an average maturity of our portfolio that should not exceed six 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 December 31, 2003, our short-term investments approximated market value.

At December 31, 2003, we had two U.S. term loans totaling $75.1 million and a European term loan of $9.9 million outstanding and $16.9 million outstanding borrowings on a U.S. revolving line of credit and $23.0 million outstanding borrowings on a European revolving line of credit under our amended senior credit agreement dated September 30, 2003. In February 2004, using the proceeds of our sale of $150 million of 8.75% senior subordinated notes we prepaid all outstanding borrowings under the amended senior credit facility while we retain $50 million availability, in the aggregate, under the revolving lines of credit. We may repay any future borrowings under the revolving lines of credit at any time but in no event later than March 31, 2008. Borrowings under the revolving lines of credit bear interest at either (i) the London Interbank Offered Rate, or LIBOR, as defined in the agreement, plus applicable margins or, at our option, (ii) a floating Index Rate, as defined in the agreement, plus applicable margins. Applicable margins if we choose to use the LIBOR or the Index Rate can range from 3.25% to 4.00% or 2.00% to 2.75%, respectively, depending on the quarterly adjustments that are based on our consolidated financial performance, commencing with the quarter ending March 31, 2004. As of December 31, 2003, the applicable interest rate under the revolving lines of credit, including the applicable margin, was 5.14%.

We have an interest rate swap agreement with a bank in place, which was intended to provide us with limited protection from fluctuations in the LIBOR rate. Under the interest rate swap agreement, the LIBOR rate is at a minimum of 3.36% and a maximum of 5% and applies to $34.8 million to $36.3 million of any of our U.S. Dollar denominated loans, depending upon the interest period, for the

remaining term of the agreement. This interest rate swap agreement is effective through December 30, 2004.

As of December 31, 2003, the LIBOR and Index rates applicable under the amended senior credit agreement were 1.14% and 4%, respectively. Assuming no changes in our leverage ratio, which would affect the margin of the interest rate under the amended senior credit agreement, and as long as we borrow only up to the amounts covered under the interest rate swap agreement, increase in the LIBOR rate by 1% point or 2% points would not affect our interest expense. However, assuming no changes in our leverage ratio, the effect of interest rate fluctuations on each $1.0 million borrowings under the revolving lines of credit in excess of the amounts covered under the interest rate swap agreement over the next twelve months is quantified and summarized as follows:

	Interest Expense Increase
If compared to the rate at December 31, 2003,	
LIBOR increases by 1% point and aggregate borrowings exceed the amount applicable under the interest rate swap agreement	$ 10,000
LIBOR increases by 2% point and aggregate borrowings exceed the amount applicable under the interest rate swap agreement	$ 20,000

Our subsidiary IMN has a credit agreement with its bank, under which it can borrow up to $15.0 million under a revolving credit commitment and $4.2 million under a term loan commitment, subject to specified borrowing base limitations. These IMN loans mature on October 15, 2004, but the maturity date is automatically extended for one year at each maturity date unless a ninety day termination notice is given in writing by either party to the agreement. As of December 31, 2003, total borrowings outstanding under the credit agreement with the bank were $13.1 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 IMN's option, at 3.75% above the Adjusted Eurodollar Rate used by the bank. As of December 31, 2003, the interest rate on $3.3 million of the outstanding borrowings was at the Adjusted Eurodollar Rate of 1.17% plus the spread of 3.75% and the interest rate on the remaining $9.9 million of the outstanding borrowings was at the prime rate of 4.00% plus the spread of 1.5%. The effect of interest rate fluctuations on the loans under IMN's credit agreement over the next twelve months, assuming the credit agreement is automatically extended for one year at the current maturity date, is quantified and summarized as follows:

	Interest Expense Increase
If compared to the rates at December 31, 2003,	
Interest rates increase by 1% point	$ 122,000
Interest rates increase by 2% points	243,000

Foreign Currency Risk

We face exposure to movements in foreign currency exchange rates whenever we, or any of our subsidiaries, enter into transactions with third parties that are denominated in currencies other than our, or its, functional currency. Intercompany transactions between entities that use different functional currencies also expose us to foreign currency risk. In 2003, the net impact of foreign currency changes on transactions was a gain of $5,000. Generally, we do not use derivative financial instruments or other financial instruments to hedge such economic exposures. However, if our foreign currency exchange exposure in these transactions continues to be significant, we may decide to use such instruments in the future.

Gross margins of products we manufacture at our European plants and sell in U.S. Dollar are also affected by foreign currency exchange rate movements. Our overall gross margin on net product sales

was 42.5% in 2003. If the U.S. dollar had been stronger by 1%, 5% or 10%, compared to the actual rates in 2003, our overall gross margin on net product sales would have been 42.7%, 43.3% and 44.1%, respectively.

In addition, because a substantial portion of our earnings is generated by our foreign subsidiaries, whose functional currencies are other than the U.S. dollar (in which we report our consolidated financial results), our earnings could be materially impacted by movements in foreign currency exchange rates upon the translation of the earnings of such subsidiaries into the U.S. dollar. If the U.S. dollar had been stronger by 1%, 5% or 10%, compared to the actual average exchange rates used to translate the financial results of our foreign subsidiaries, our net revenue and net income would have been lower by approximately the following amounts:

	Approximate Decrease in	
	Net Revenue	Net Income
If during 2003, the U.S. dollar was stronger by:		
1%	$ 804,000	$ 23,000
5%	4,018,000	117,000
10%	8,036,000	234,000

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements and supplementary data are listed under Item 15(a) and have been filed as part of this report on the pages indicated.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

The disclosure called for by paragraph (a) of Item 304 of Regulation S-K has been previously reported in (i) our Current Report on Form 8-K, dated and filed June 28, 2002, relating to our dismissal of Arthur Andersen LLP and our engagement of Ernst & Young LLP as our independent auditors, and (ii) our Current Report on Form 8-K, dated April 11, 2003 and initially filed on April 18, 2003, as amended on May 29, 2003, relating to the resignation of Ernst & Young LLP and our engagement of BDO Seidman, LLP as our independent auditors.

ITEM 9A. CONTROLS AND PROCEDURES

Conclusions regarding the effectiveness of our disclosure controls and procedures

Our management evaluated, with the participation of our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), the effectiveness of the design and operation of the Company's disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this annual report on Form 10-K. Based on this evaluation, our management, including the CEO and CFO, concluded that the Company's disclosure controls and procedures were effective at that time. We and our management understand nonetheless that controls and procedures, no matter how well designed and operated, can provide only reasonable assurances of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating and implementing possible controls and procedures. In reaching their conclusions stated above regarding the effectiveness of our disclosure controls and procedures, our CEO and CFO concluded that such disclosure controls and procedures were effective as of such date at the "reasonable assurance" level.

Changes in internal control over financial reporting

There was no change in our internal control over financial reporting that occurred during our fourth fiscal quarter of 2003 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. As part of our ongoing efforts to enhance our controls and procedures, however, we have taken certain actions during 2003 which may directly or indirectly affect our internal control over financial reporting. In July 2003, we engaged Protiviti, Inc., an independent risk consulting firm, to assist us in assessing, documenting and testing our internal controls starting in 2003 to ensure that we can comply with the rules and regulations promulgated under Section 404 of the Sarbanes-Oxley Act of 2002 when they take effect for us for the fiscal year ended December 31, 2004. We are also continually striving to improve our management and operational efficiency, manage our growth and integrate acquired businesses and we expect that our efforts in these regards may from time to time directly or indirectly affect our internal controls. In that regard, we hired Christopher Lindop as our Chief Financial Officer during the third quarter of 2003 and we have added significant additional capacity and expertise to our finance, tax and legal staff. We have also integrated the financial accounting systems of certain of our businesses with the system used by our corporate finance team and upgraded the information technology capabilities of certain of our subsidiaries.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information regarding our directors and executive officers included in our definitive Proxy Statement to be filed pursuant to Regulation 14A in connection with our 2004 Annual Meeting of Shareholders (the Proxy Statement) is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information regarding executive compensation included in the Proxy Statement is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information regarding security ownership of certain beneficial owners and management included in the Proxy Statement is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information regarding certain relationships and related transactions included in the Proxy Statement is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information regarding principal accounting fees and services included in the Proxy Statement is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES, AND REPORTS ON FORM 8-K

(a)

1. Financial Statements.

The financial statements listed below have been filed as part of this report on the pages indicated:

2. Financial Statement Schedules.

All schedules for which provision is made in the applicable accounting regulation of the Securities and Exchange Commission are not required under the related instructions or are inapplicable and have been omitted.

3. Exhibits.

2.1 Sale Agreement, dated December 20, 2001, between Inverness Medical Innovations, Inc. (the "Company") and Unilever U.K. Holdings Limited (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated December 20, 2001)

2.2 Amendment to Agreement and Plan of Merger dated as of February 18, 2003, by and among Inverness Medical Innovations, Inc., Geras Acquisition Corp. and Ostex International, Inc. (incorporated by reference to Exhibit 99.2 to the Company's Current Report of Form 8-K dated February 19, 2003)

2.3 Stock Purchase Agreement, dated as of July 30, 2003, by and among Inverness Medical Innovations, Inc., Applied Biotech, Inc. and Erie Scientific Company (incorporated by reference to Exhibit 2.1 to the Company's Current Report of Form 8-K dated August 27, 2003)

2.4 Asset Purchase Agreement, as of September 30, 2003, by and among Abbott Laboratories and Inverness Medical Innovations, Inc. and Inverness Medical Switzerland GmbH, Morpheus Acquisition Corp. and Morpheus Acquisition LLC. (incorporated by reference to Exhibit 2.1 to the Company's Current Report of Form 8-K dated September 30, 2003)

3.1 Amended and Restated Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

3.2 Certificate of Designation, Preferences and Rights of Series A Convertible Preferred Stock of the Company (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K dated December 20, 2001)

3.3 Amended and Restated By-laws of the Company (incorporated by reference to Exhibit 3.3 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

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4.1	Specimen certificate for shares of Common Stock of the Company (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-4, as amended (File No. 333-67392))
4.2	Registration Rights Agreement, as of September 30, 2003, by and among Inverness Medical Innovations, Inc. and Abbott Laboratories (incorporated by reference to Exhibit 99.2 to the Company's Current Report of Form 8-K dated September 30, 2003)
*4.3	Indenture, dated as of February 10, 2004, between Inverness Medical Innovations, Inc., the Guarantors named therein and U.S. Bank Trust National Association
*4.4	Registration Rights Agreement, as of February 10, 2004, by and among Inverness Medical Innovations, Inc., the guarantors named therein and UBS Securities LLC and Merrill Lynch, Pierce, Fenner & Smith Incorporated
10.1	Post-Closing Covenants Agreement, dated as of November 21, 2001, by and among Johnson & Johnson, IMT, the Company, certain subsidiaries of IMT and certain subsidiaries of the Company (incorporated by reference to Exhibit 10.1 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
10.2	Tax Allocation Agreement, dated as of November 21, 2001, by and among Johnson & Johnson, IMT and the Company (incorporated by reference to Exhibit 10.2 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
10.3	Supply of Goods Agreement, dated July 28, 1998, between Schleicher & Schuell GmbH and Unipath Limited (incorporated by reference to Exhibit 10.3 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
10.4	Lease, dated as of January 12, 1999, by and among Cambridge Diagnostics Ireland Limited and the Industrial Development Agency (Ireland) (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-4, as amended (File No. 333-67392))
10.5	Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-4, as amended (File No. 333-67392))
10.6	Inverness Medical Innovations, Inc. 2001 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-4, as amended (File No. 333-67392))
10.7	Inverness Medical Innovations, Inc. 2001 Employee Stock Purchase Plan First Amendment (incorporated by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
10.8	Restricted Stock Agreement under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan, dated as of August 15, 2001, between the Company and Ron Zwanziger (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
10.9	Promissory Note, dated August 16, 2001, from Ron Zwanziger to the Company (incorporated by reference to Exhibit 10.12 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)
10.10	Pledge Agreement, dated as of August 16, 2001, between Ron Zwanziger and the Company (incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

10.11 Non-Qualified Stock Option Agreement under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan, dated as of August 15, 2001, between the Company and Jerry McAleer (incorporated by reference to Exhibit 10.3 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

10.12 Promissory Note, dated December 4, 2001, from Jerry McAleer to the Company (incorporated by reference to Exhibit 10.15 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

10.13 Pledge Agreement, dated as of December 4, 2001, between Jerry McAleer and the Company (incorporated by reference to Exhibit 10.16 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

10.14 Non-Qualified Stock Option Agreement under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan, dated as of August 15, 2001, between the Company and David Scott (incorporated by reference to Exhibit 10.17 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

10.15 Promissory Note, dated December 4, 2001, from David Scott to the Company (incorporated by reference to Exhibit 10.18 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

10.16 Pledge Agreement, dated as of December 4, 2001, between David Scott and the Company (incorporated by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

10.17 Stock Purchase Agreement, dated as of December 14, 2001, between the Company and the investors named therein (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K dated March 14, 2002)

10.18 Note and Warrant Purchase Agreement, dated as of December 14, 2001, between the Company and the investors named therein (incorporated by reference to Exhibit 99.3 to the Company's Current Report on Form 8-K dated December 20, 2001)

10.19 Form of Subordinated Promissory Note issued pursuant to the Note and Warrant Purchase Agreement dated as of December 14, 2001 (incorporated by reference to Exhibit 99.4 to the Company's Current Report on Form 8-K dated December 20, 2001)

10.20 Form of Warrant for the Purchase of Shares of Common Stock of the Company issued pursuant to the Note and Warrant Purchase Agreement dated as of December 14, 2001 (incorporated by reference to Exhibit 99.5 to the Company's Current Report on Form 8-K dated December 20, 2001)

10.21 Warrant for the Purchase of Shares of Common Stock of the Company, dated as of December 20, 2001, issued to Zwanziger Family Ventures, LLC (incorporated by reference to Exhibit 10.28 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

10.22 Loan and Security Agreement, dated as of October 16, 2000, between IVC and Congress Financial Corporation (incorporated by reference to Exhibit 10.29 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

10.23 Amendment No. 1 to Loan and Security Agreement, dated June 13, 2001, by and between Congress Financial Corporation and IVC (incorporated by reference to Exhibit 10.30 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

10.24 Amendment No. 2 to Loan and Security Agreement, dated as of June 14, 2001, by and between Congress Financial Corporation and IVC (incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

10.25 Amendment No. 3 to Loan and Security Agreement, dated as of March 19, 2002, by and between Congress Financial Corporation and IVC (incorporated by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

10.26 Agreement, dated December 1, 1986, between Bernard Levere, Zelda Levere, Pioneer Pharmaceuticals, Inc. and Essex Chemical Corp. and Unconditional Guarantee by Essex Chemical Corp. (incorporated by reference to Exhibit 10.33 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

10.27 Option to Assume and Extend Lease, dated as of February 1995, between Bernard Levere, Zelda Levere and International Vitamin Corporation (incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

10.28 Inverness Medical Innovations, Inc. Executive Bonus Plan (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-4, as amended (File No. 333-67392))

10.29 Licensing Agreement, dated March 14, 1988, between Unilever Plc and Behringwerke AG (incorporated by reference to Exhibit 10.37 to the Company's Annual Report on Form 10-K, as amended, for the period ended December 31, 2001)

10.30 Supplemental Agreement, dated October 16, 1994, between Unilever Plc, Unilever NV and Behringwerke AG (incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K, as amended, for the period ended December 31, 2001)

10.31 Supply of Goods Agreement, dated December 19, 1994, between AFC Worldwide and Unipath Limited (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, as amended, for the period ended March 30, 2002)

10.32 Amendment to Supply of Goods Agreement, dated March 14, 2002, between Schleicher & Schuell GmbH and Unipath Limited (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, as amended, for the period ended March 30, 2002)

10.33 Amendment No. 1 to Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-8 (File No. 333-90530))

10.34 Subordinated Note and Warrant Purchase Agreement dated as of September 20, 2002 between the Company and the investors named therein ("Note and Warrant Purchase Agreement") (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K dated September 20, 2002)

10.35 Form of Subordinated Promissory Note issued pursuant to the Note and Warrant Purchase Agreement (incorporated by reference to Exhibit 99.2 to the Company's Current Report on Form 8-K dated September 20, 2002)

10.36 Form of Warrant Agreement issued pursuant to the Note and Warrant Purchase Agreement (incorporated by reference to Exhibit 99.3 to the Company's Current Report on Form 8-K dated September 20, 2002)

10.37	Subordinated Note Purchase Agreement dated as of September 20, 2002 between the Company and the investors named therein ("Note Purchase Agreement") (incorporated by reference to Exhibit 99.4 to the Company's Current Report on Form 8-K dated September 20, 2002)
10.38	Form of Subordinated Promissory Note issued pursuant to the Note Purchase Agreement (incorporated by reference to Exhibit 99.5 to the Company's Current Report on Form 8-K dated September 20, 2002)
10.39	Form of Convertible Subordinated Promissory Note issued pursuant to the Note Purchase Agreement (incorporated by reference to Exhibit 99.6 to the Company's Current Report on Form 8-K dated September 20, 2002)
10.40	Second Amended and Restated Credit Agreement, dated as of September 30, 2003, by and among Inverness Medical Innovations, Inc., Wampole Laboratories, Inc., Inverness Medical (UK) Holdings Limited, the other Credit Parties Signatory thereto, the lenders signatory thereto from time to time, General Electric Capital Corporation, as administrative agent for lenders, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as co-syndication agent, UBS AG, Stamford Branch, as co-syndication agent, and GECC Capital Markets Group, Inc. and ML Capital, as co-lead arrangers (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q dated November 14, 2003)
*10.41	First Amendment and Consent to Second Amended and Restated Credit Agreement, dated as of November 17, 2003, by and among General Electric Capital Corporation, as agent and lender, Inverness Medical Innovations, Inc., Wampole Laboratories, Inc. and Inverness Medical (UK) Holdings Limited, as borrowers, the other credit parties signatory thereto, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as documentation agent and co-syndication agent, UBS Securities LLC, as co-syndication agent, and the lenders signatory thereto from time to time
*10.42	Second Amendment to Second Amended and Restated Credit Agreement, dated as of December 31, 2003, by and among General Electric Capital Corporation, as agent and lender, Inverness Medical Innovations, Inc., Wampole Laboratories, Inc. and Inverness Medical (UK) Holdings Limited, as borrowers, the other credit parties signatory thereto, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as documentation agent and co-syndication agent, UBS Securities LLC, as co-syndication agent, and the lenders signatory thereto from time to time
*10.43	Commercial Lease, dated August 1, 1998, by and between The Chang Family Trust and Applied Biotech, Inc.
*10.44	Amendment to Commercial Lease, dated April , 2003, by and between The Chang Family Trust and Applied Biotech, Inc.
*10.45	Manufacturing, Packaging and Supply Agreement, dated as of June 6, 2003, among Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH, Unipath, Ltd. and Warner-Lambert Company LLC+
*10.46	First Amendment to Subordinated Promissory Notes, dated as of November 14, 2003
*10.47	First Amendment to Convertible Subordinated Promissory Notes, dated as of January 15, 2004
*14.1	Inverness Medical Innovations Business Conduct Guidelines
*21.1	List of Subsidiaries of the Company as of March 15, 2004
**23.1	Consent of BDO Seidman, LLP