
# inverness medical innovations INC

## 2002 ANNUAL REPORT

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*advancing health at the speed of life*

*Dear Shareholders, Friends and Fellow Employees:*

Our first full year at Inverness Medical Innovations can best be summed up in one word - ***Progress.***

Our progress during 2002 was marked by accomplishments driven by the attributes perfected and valued by our management team over many years of working together, namely:

***early speed*** - in identifying and acquiring companies and technologies that form integral components of our ongoing strategy;

***steady advancement*** -in the successful integration of acquired businesses and the work of our research and development teams;

***strong finish*** - in delivering solid financial performance.

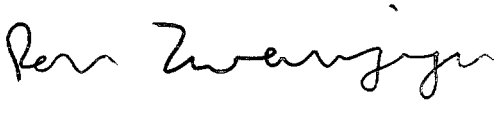
Operationally, we exceeded even our own expectations regarding the speed with which we were able to integrate three acquired businesses. Specifically, our acquisition and quick integration of IVC Industries garnered a meaningful presence in the mass-merchandise nutritional market and substantial manufacturing capacity that has allowed us to internally consolidate our nutritional operations. Our already successful assimilation of Wampole Laboratories, purchased in September 2002, is providing us with important intellectual property as well as a formidable presence in "point-of-care" markets with extended distribution capabilities to hospitals, physicians and reference laboratories.

Perhaps our most significant achievement of the year was the effective fusion of our existing business, intellectual property and other assets with those of our Unipath unit, acquired in December 2001. This now seamless integration has put us in a position to accelerate our research and product development plans. Specifically, we announced during the year that we had moved up our anticipated launches of transformational product advancements in the areas of women's health, infectious diseases and cardiology. In particular, we charted a course that includes the introduction of a new digital pregnancy test before the end of 2003 and an increased sensitivity strep throat test during the first half of 2004.

As we continue into 2003 and beyond, we remain committed to advancing health through a continual flow of innovative new products driven by our strategy of investing in research and development, intellectual property, manufacturing and market access. That strategy has served us well in providing our current strong foundation for growth with:

- Brand prominence in the pregnancy and ovulation markets;
- World class R&D facilities and teams;
- Strong positions in intellectual property; and
- Multiple manufacturing facilities and distribution capabilities worldwide.

It is from this platform that we approach the future committed to our vision to be the leading provider of innovative diagnostic products for women's health and chronic disease self-management. As always we thank our employees, partners and shareholders for their past and ongoing support and confidence.



Ron Zwanziger
Chairman, Chief Executive Officer
and President

# SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

# FORM 10-K

## FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

(Mark One)

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

For the fiscal year ended December 31, 2002

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

*Commission file number 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 ☒ No ☐

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. ☐

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

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 28, 2002 (the last business day of the registrant's most recently completed second fiscal quarter) was $176,074,593. 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 28, 2003, the registrant had 15,007,336 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 30, 2003 are incorporated by reference into Part III of this Form 10-K.

## 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. Readers can identify these statements by forward-looking words such as "may," "could," "should," "would," "intend," "will," "expect," "anticipate," "believe," "estimate," "continue" or similar words. There are a number of important factors that could cause actual results of Inverness Medical Innovations, Inc. and its subsidiaries to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, the risk factors detailed in this annual report on Form 10-K and other risk factors identified from time to time in our periodic filings with the Securities and Exchange Commission. Readers should carefully review the factors discussed in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations—Certain Factors Affecting Future Results" and "Special Statement Regarding Forward-Looking Statements" beginning on pages 38 and 53, respectively, in this annual report on Form 10-K 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" and "our" refer to Inverness Medical Innovations, Inc. and its subsidiaries.*

### ITEM 1. BUSINESS

#### OVERVIEW

Our company, Inverness Medical Innovations, Inc., a Delaware corporation, was initially formed in May 2001 as a wholly owned subsidiary of Inverness Medical Technology, Inc., or IMT. On November 21, 2001, as part of a split-off and merger transaction in which Johnson & Johnson acquired IMT's diabetes business, we acquired all of IMT's non-diabetes businesses, i.e., its women's health, nutritional supplements and professional diagnostics businesses, and were split-off from IMT as a separate publicly traded company.

We develop, manufacture and market consumer healthcare products, including self-test diagnostic products for the women's health market and vitamins and nutritional supplements. We also develop, manufacture and distribute a wide variety of diagnostic products for use by medical and laboratory professionals.

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

In September 2002, we significantly expanded our professional diagnostics business by acquiring the Wampole Laboratories division of MedPointe Inc. Wampole is a leader in enzyme linked immuno

sorbent assay (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, physician's offices and clinics through an extensive U.S. distribution network and these products compliment our existing professional diagnostic products lines and international distribution networks.

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.invernessmedical.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

*Pending Merger with Ostex International, Inc.*

On September 6, 2002, we entered into an agreement and plan of merger with Ostex International, Inc. pursuant to which we intend to acquire Ostex. Ostex develops and commercializes osteoporosis diagnostic products. Our pending acquisition of Ostex is subject to several closing conditions, including approval of the merger agreement governing the acquisition by Ostex's shareholders and our receipt of any necessary consents with respect to the transactions contemplated by the merger agreement required under any of our material loan agreements. On February 18, 2003, in order to increase the likelihood that we would obtain the consent of our senior lender to the merger, as required under our material loan agreements, we and Ostex amended the merger agreement to reduce the consideration we will pay to acquire Ostex. Under the merger agreement, as amended, the aggregate number of shares of our common stock to be issued in the merger for Ostex's outstanding shares and to be reserved for options and warrants to be assumed is 1.9 million shares. Under the amended merger agreement, at the effective time of the merger, each outstanding share of Ostex common stock will be converted into the right to receive a number of shares of our common stock equal to a conversion ratio that is to be calculated by dividing 1.9 million by the sum of (1) the total number of shares of Ostex common stock outstanding immediately prior to the effective time of the merger; and (2) the total number of shares of Ostex common stock subject to outstanding stock options and warrants that we are to assume in the merger. The shares of Ostex common stock subject to options and warrants to be assumed by us will convert at the same ratio. The merger remains subject to approval by the holders of two thirds of Ostex's outstanding voting stock, the receipt of third-party consents, including the consent of our senior lender, and other customary closing conditions, so there can be no assurance that our acquisition of Ostex will occur.

*Preliminary Injunctions against Pfizer*

On December 19, 2002, the United States District Court for the District of New Jersey entered an order granting our motion for a preliminary injunction against Pfizer, Inc., based on a finding that Pfizer's e.p.t® pregnancy tests, as manufactured by ABI, a subsidiary of Apogent, Inc., likely infringe U.S. Patent No. 6,352,862. The Court further denied Pfizer's request for a stay of the injunction pending appeal, which Pfizer has since filed. We posted a bond of $3.5 million in December 2002 as required by the Court and this injunction is in effect.

On March 12, 2003, the Court granted a subsequent preliminary injunction against Pfizer, Inc., based on a finding that a new version of Pfizer's e.p.t. pregnancy tests manufactured by Mizuho USA, Inc., a subsidiary of Mizuho Medy, Ltd., also likely infringes the same patent, as well as another patent owned by our subsidiary, Inverness Medical Switzerland GmbH. The Court also denied Pfizer's request for a stay of this injunction pending appeal. The Court has required that we post an additional bond in the amount $35 million before this injunction will become effective.

The Court's orders effectively preclude Pfizer from selling either of these versions of its e.p.t. pregnancy tests pending appeal upon posting of the respective bonds. The orders do not prohibit Pfizer from finding new sources of supply.

## BUSINESS SEGMENTS AND GEOGRAPHIC AREA

Our major reportable operating segments are consumer products and professional diagnostics. Our consumer products are further divisible into self-test diagnostic products and vitamins and nutritional supplements. We further categorize our sales by major geographic areas of the world. Below are discussions of each of our operating segments. Financial information about our business segments is provided in Note 14 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 women's health market. A.C. Neilsen & Co. estimates total United States retail sales of pregnancy and ovulation prediction tests at approximately $282 million for the 52 weeks ending February 22, 2003, approximately 85% of which represents sales of pregnancy detection tests and approximately 15% of which represents sales of ovulation prediction tests. The demand for ovulation prediction products is growing steadily because of increased awareness of the incidence of infertility and a desire on the part of couples to plan conception with more certainty. The demand for pregnancy test products is growing also, but at a slower pace.

There are numerous pregnancy self-tests on the market, which are typically urine-based tests and provide results in less than five minutes. Ovulation prediction tests inform women of the best time to conceive a baby by detecting the surge of the luteinizing hormone, which precedes ovulation. Ovulation prediction tests are generally easy to use and urine-based ovulation predictions tests have become widely accepted by professional fertility care providers and the general public. Urine-based 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 reusable monitoring device which measures estrogen levels as well as the luteinizing hormone. There are also saliva-based 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, generally experience relatively slow and stable growth. 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 store brand, or private label, products has 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 allow qualitative and/or quantitative analysis of the patients body fluids or tissue for evidence of specific medical conditions, disease states or to measure response to therapy.

Customers in this market can be divided into several distinct groups. One such group consists of large, centralized laboratories offering wide-ranging clinical laboratory services in hospital or related settings. These are frequently characterized by very significant levels of test automation and integration of information systems. As high-throughput facilities their product requirements often vary from those of other customer groups such as small and medium-sized, non-centralized laboratories and testing locations. Examples in this latter category include physician office laboratories, small blood banks, specialist mobile clinics and some rapid-response laboratories in larger medical centers.

We believe that the demand for infectious disease diagnostic products is growing faster than demand in many other segments of the point-of-care immunoassay market due to the increasing incidence of certain diseases or groups of diseases, including lyme disease, viral hepatitis, acquired immuno deficiency syndrome and tuberculosis, as well as chlamydia and other sexually transmitted diseases. Furthermore, it is generally accepted that the emerging field of theranostics (the use of diagnostic assays to monitor and assess a patient's response to therapy) is one of the fastest growth areas in the broad in vitro diagnostics marketplace.

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. Efforts of insurers and government agencies world-wide to control health care costs also play a large role in the increasing demand for fast, efficient results.

## Products

*Consumer Products*

*Consumer Diagnostics.* Our consumer diagnostics business currently develops, manufactures and markets home pregnancy and ovulation prediction tests under our own brands and under various private labels. Our Clearblue® home pregnancy detection and ovulation prediction tests are global leaders in terms of both sales and technology and our Clearblue Easy® Fertility Monitor is the leading reusable monitoring device available to assist women attempting to conceive. Until recently our Clearblue ovulation prediction products were marketed under the ClearPlan® and ClearPlan Easy® labels. Our Accu-Clear™ branded products are marketed to value-oriented consumers in the United States. In addition, we are a major United States supplier of private label home pregnancy detection and ovulation prediction products. We also sell Persona®, a contraceptive monitoring device sold overseas, 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 employ identical technology enabling the display of visual results in approximately three minutes. We sell

pregnancy test kits over-the-counter through drugstore chains, grocery chains and mass merchandisers under their own store brand label as well as under our own brand names.

- *Ovulation Prediction Products.* We market our 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 ovulation prediction test kits under our own brand names and under various store brand labels of retail drugstore chains, grocery stores and mass merchandisers. Our 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 their family planning. Clinically accurate results are available in approximately three minutes.

  We also market an advanced ovulation prediction self-test device called the Clearblue Easy Fertility Monitor. The Fertility Monitor not only detects the surge of the luteinizing hormone (LH), which causes ovulation, but it is also the only ovulation prediction device that identifies additional days when a woman can 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 an in-vitro diagnostic monitoring device that serves as 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 classed as a contraceptive device. We do not have, and we have not applied for, regulatory approval to sell Persona in the United States.

  Clearblue, Clearblue Easy, ClearPlan, ClearPlan Easy, Persona and Accu-Clear are trademarks of Inverness Medical Switzerland GmbH.

*Vitamins and Nutritional Supplements.* We market a wide variety of vitamins and nutritional supplements through retail drug store chains, mass merchandisers, food stores and warehouse clubs primarily within the United States and Canada. Inverness Medical Nutritionals Group, or IMN, is a leading 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 a comprehensive assortment of vitamin, mineral and nutritional supplement products for sale under Inverness Medical brand names.

Our Inverness Medical branded nutritional products are primarily high quality products sold at moderate prices through national and regional drug stores, supermarkets and mass merchandising chains. 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®, 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.

SmartCare is a registered trademark of Inverness Medical, Inc. ALLBEE, Posture, Protegra, SoyCare, Stresstabs and Z-BEC are U.S. trademarks of Inverness Medical, Inc., which also licenses the North American rights to Ferro-Sequels.

*Professional Diagnostic Products*

With our acquisition of Wampole Laboratories, we now develop and market a broad range of diagnostic test kits and instrumentation to professional diagnostic users. In the United States our professional diagnostic products are sold under our Wampole® and Clearview® labels and we also distribute products on behalf of third parties. We market our Clearview products worldwide and we sell several proprietary platforms of products manufactured by our subsidiary Orgenics, Ltd., located in Yavne, Israel, outside of the United States. Our professional diagnostic products include:

- *ELISA Products*. We offer over 60 enzyme linked immuno sorbent assay (ELISA) tests for infectious and sexually transmitted disease, 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 (VZV) and Legionella; enteric disease testing for C.difficile, Giardia, Cryptosporidium, and E. histolytica; chlamydia; autoimmune disease 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 U.S. as a low cost alternative that provides the sensitivity, accuracy and versatility of more expensive automated ELISA platforms.

- 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 (ANA) screen and reflex testing for nine specific autoantibodies 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, automation-friendly format.

- *Rapid Membrane Test Products*. We also develop and market a wide variety of rapid membrane products test for pregnancy, mononucleosis, C.difficile, lyme disease, chlamydia, H.pylori, Group A Streptococcus and rubella. These products, which include our Clearview brand, 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.

- *IFA and Microbiology Products*. We also offer a complete line of indirect fluorescent antibody, or IFA, assays for viral, bacterial and autoimmune diseases. Our Isolator® Blood Culture system provides faster isolation and improved recovery of microorganisms in the blood and our MicroTrak® family of sexually transmitted disease products include Chlamydia EIA, as well as Chlamydia DFA and herpes simplex virus tests.

- *Serology Products*. We also offer a comprehensive 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.

Wampole and Isolator are trademarks of Wampole Laboratories, Inc. Clearview is a trademark of Inverness Medical Switzerland GmbH. ImmunoComb, DoubleCheck and ImmunoGold are trademarks of Orgenics Ltd. Labotech, PersonalLAB, MicroTrak and AtheNA Multi-Lyte are trademarks of their respective owners.

**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 store chains, drug wholesalers, grocery retailers and mass merchandisers in North America, Europe and Japan. Our Clearblue brand pregnancy detection and ovulation prediction test products, which are marketed under the name Clearblue Easy in the United States, are leading brands both in the United States and globally. With the exception of our Clearblue Easy pregnancy tests in the United States, 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 TV, radio and magazine advertising. Within the United States, our Clearblue Easy pregnancy tests are not established as a premium brand because they have yet to acquire the level of brand awareness and brand loyalty typical of a premium brand. We are attempting to build market share by pricing our Clearblue pregnancy tests below the premium brands as well as through aggressive mass media advertising of the brand. Our Accu-Clear brand products compete primarily based on price and are not heavily advertised. Our consumer diagnostics products are marketed in the United States, the UK 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 arrangements accounted for 19% of our consumer diagnostics business' net product sales for 2002. Our five largest customers during 2002 based on net product sales were Walgreen Co., Boots Company, CVS Corporation, Schering AG and Mitsui & Co.

*Vitamins and Nutritional Supplements.* We primarily market and sell our vitamins and nutritional supplements in the United States and Canada through private label arrangements with retail drug store chains, drug wholesalers, grocery retailers and mass merchandisers who sell our products under their store brands. We also sell a variety of branded products to the same types of retailers. To a much lesser extent we provide contract manufacturing services to third parties. Our three largest customers during 2002 were Walgreen Co., Costco and Eckerd Drug. Our rights to the trademarks Stresstabs, Ferro-Sequels, Posture, 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 in North America under other brand names outside of North America.

*Professional Diagnostics Products*

In the United States, we distribute our professional diagnostics products to hospitals, major reference testing laboratories, physician's offices and clinics through the extensive distribution network we acquired with Wampole Laboratories. For the calendar year 2002, the three largest customers of our U.S. professional diagnostics business were Cardinal Health, Quest Diagnostics and Laboratory Corporation of America.

Outside the United States, we sell our Clearview products through third party distributors, except in Germany, where we have our own sales force. We also sell a C.difficile Toxin A 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 78% of our sales of Clearview products.

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 more than 90 countries, principally in Europe, Latin America, Africa and Asia.

Other than our Clearview products, which we develop and manufacture in Bedford, England, and our Orgenics products, which we manufacture in Israel, our professional diagnostics products are manufactured by third parties and, in some cases, our distribution rights are limited to the United States. Our Orgenics products, as well as several of our Clearview products, are not approved for sale, and are not sold, in the United States.

**Manufacturing**

*Consumer Products*

*Consumer Diagnostic Products.* We produce our disposable consumer diagnostic products at our facilities in Bedford, England and Galway, Ireland. Both facilities are ISO 9001 and EN 46001 certified, FDA registered establishments that employ modern production techniques to produce consistent, high-quality components. A significant portion of our products produced and assembled at our Galway plant is subsequently packaged by a third party in the United States. We rely on third parties for nearly all our production materials. We purchase our electronic, consumer diagnostic products, the Clearblue Easy Fertility Monitor and Persona, to our specifications from third party suppliers in Europe. Because most components of our diagnostic products are produced to our specifications, some of our suppliers are single source suppliers with few, if any, alternative sources immediately available.

We own one-half and lease one-half of our Galway facility and 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 "Item 2—Description of Property" and the related risk factor on page 14.

*Vitamins and Nutritional Supplements.* IMN manufactures substantially all of our vitamin and nutritional products at its 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 all of its softgel requirements at the Irvington facility. Our Freehold facility manufactures in full compliance with Good Manufactures Practice, or 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 an FDA registered facility.

*Professional Diagnostics Products*

Greater than 65% of the professional diagnostic products that we sell, based on net product sales for fiscal year 2002, are manufactured by third parties. 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. The Yavne manufacturing facility is ISO 9001 and EN 46001 certified, as well as Good Manufacturing Practices certified by the Israeli Ministry of Health.

**Research and Development**

We intend to focus our research and development efforts on the development of new products and enhanced features for our lines of women's health and professional diagnostics products, as well as the development of product lines targeting new markets, primarily in cardiology. Currently the majority of our budget for research and development is allocated to new product development. Most of our research and development activities are carried out in Bedford, England, Galway, Ireland and Yavne, Israel. 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 manufacturing facilities are outside the United States, in Bedford, England, Galway, Ireland and Yavne, Israel. Approximately 42% of our net revenues were generated from outside of the United States during 2002. Our Clearblue products, pregnancy tests in particular, have historically been much stronger brands outside the United States, with 68% of our net product sales of Clearblue products coming from outside the United States during 2002. In addition, IMN generated almost 17.5% of its net product sales outside of the United States during 2002. 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. However, Wampole Laboratories, which we acquired in September 2002, was primarily a U.S. distribution business and has historically had very little revenue from foreign operations. While our international distribution networks may allow us to expand the scope of Wampole's sales territory, we cannot guarantee that this will happen.

## 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 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 main competitors for the sale of pregnancy test products in the United States include Abbott Laboratories, Armkel, Becton Dickinson and Pfizer, Inc., although Pfizer, Inc., whose e.p.t pregnancy test is the market leader in the United States, has recently been preliminarily enjoined (pending appeal) from selling e.p.t. in the United States (See "Recent Developments—*Preliminary Injunctions Against Pfizer, Inc.*" on page 3 hereof). Other competitors include Acon Laboratories, London International Holdings, Inc., Omega Pharma, Princeton BioMeditech Corporation, Rhoto Pharmaceutical Co., Syntron Bioresearch and Quidel Corp. Our competitors for the sale of ovulation predictors include Armkel, Apogent, Princeton BioMeditech, Syntron and Quidel. Competition among branded consumer diagnostics 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. Outside of the United States, Clearblue is a premium brand and is a market leader. In the United States, where our Clearblue pregnancy tests are less well-established, the premium brands can demand higher pricing than we can, even though Clearblue constitutes a leading brand that is marketed based on brand development. Our Clearblue ovulation prediction products qualify as premium brands worldwide and are market leaders both in the United States and globally. Our 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.

Many 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 Pharmavite, Leiner Health Products, Royal Numico, Bayer and NBTY, 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 supermarkets and other mass retailers are Wyeth, Pharmavite, Leiner Health Products, Royal Numico, NBTY and SmithKline Beecham.

*Professional Diagnostic Products*

Our competitors for the ELISA diagnostics market include large corporations, such as Abbott Laboratories, Diagnostic Products Corporation and Ortho-Clinical Diagnostics, 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 Meridian Bioscience 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 in developing nations, competes against automated ELISA systems based on price.

In the rapid membrane market, our main competitors are Abbott Laboratories, Becton Dickinson, Quidel Corporation and Beckman Coulter. Some competitors in this market, such Abbott and 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 Corporation, Applied Biotech, Vedalab 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.

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, S.A. and Quidel Corporation. 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 ability to obtain patent protection for our products and manufacturing processes to preserve our trade secrets and to avoid infringing the proprietary rights of third parties.

We hold certain patent rights and expect to seek additional patents in the future. However, we cannot assure you as to our success or timeliness in obtaining any such patents or as to the breadth or degree of protection that any such patents might afford us. The patent position of medical products and diagnostic testing firms is often highly uncertain and usually involves complex legal and factual questions. There is a substantial backlog of patents at the United States Patent and Trademark Office and in other patent registration offices around the world. No consistent policy has emerged regarding the breadth of claims covered in medical product patents. Accordingly, we cannot assure you that patent applications relating to our products or technology will result in patents being issued, that, if issued, such patents will afford adequate protection to our products or that our competitors will not be able to design around such patents.

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 could and have incurred substantial costs both in asserting infringement claims against others and in defending ourselves against patent infringement claims. We expect to continue to incur substantial litigation costs as we continue to aggressively protect and defend our proprietary rights. We currently have approximately twenty 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 United States 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 in our consumer products product lines are valuable assets and 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 Food and Drug Administration (FDA) and corresponding foreign regulatory authorities. The marketing of our consumer diagnostic products is also subject to regulation by the Federal Trade Commission (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 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 26, 2003, we had a total of 1,187 full-time employees, of which 488 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 $74,000. The sublease covering this space expires on May 30, 2003, although we have entered into a five year lease with the owner of this space that will commence upon the expiration of our current sublease. The initial monthly rent under this new lease will be approximately $43,000.

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 and serving as our research and development center. This facility contains fully automated assembly equipment, and state-of-the-art research laboratories, with excess space and 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, $2.35 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, 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. 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 houses the manufacturing of our Accu-Clear brands and most of our private label pregnancy detection and ovulation prediction test products, as well as some research and development. Aggregate annual mortgage and lease payments for our Galway facility total approximately $175,000.

The FDA regulates companies that manufacture commercial medical devices and requires that such companies manufacture such devices in a properly designed and validated environment. A registered facility is required to submit to an FDA inspection not less than once every two years. As required by the regulations, each of the above-described facilities have been registered with the FDA and are Good Manufacturing Practices compliant. The Bedford facility operates to international standards of Good Manufacturing Practice, Good Laboratory Practice, Good Clinical Practice and Quality Assurance (ISO 9001, EN 46001 and ISO 13485). Our Galway facility is also ISO 9001, EN 46001 and ISO 13485 certified.

We also house the development, manufacturing, administrative and marketing operations related to our Orgenics professional diagnostics products in a leased facility of approximately 10,000 square feet in Yavne, Israel. The lease for this facility expires in 2006 and carries rent of $25,000 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. Our Yavne facility is ISO 9001, EN 46001 and Good Manufacturing Practices certified.

We also lease a 130,000 square foot facility in Freehold, New Jersey, which has served as IMN's primary warehouse and distribution facility. This lease expires on July 27, 2008 and the current monthly rent is approximately $43,333. We sublease approximately 30,000 square feet of this facility to a third party. We have also recently signed a letter of intent to lease a 30,000 square foot warehouse in Irvington, New Jersey to support our softgel manufacturing operation, which is located next door. We also have leases or other arrangements for administrative offices, lab space and warehouses in New Jersey (Princeton, Cranbury and Springfield), British Columbia (Surrey), 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

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

In April 1998, Abbott Laboratories ("Abbott") commenced a lawsuit against Inverness Medical Technology, Inc. ("IMT"), our former parent and formerly known as Selfcare, Inc., and Princeton BioMeditech Corporation ("PBM"), which previously manufactured certain products for IMT, in an action filed in the United States District Court for the District of Massachusetts ("District Court"). In the lawsuit Abbott asserts patent infringement arising from IMT's and PBM's manufacture, use and sale of products that Abbott claims are covered by one or more of the claims of U.S. Patent Nos. 5,073,484, 5,654,162 and 6,020,147 (the "Pregnancy Test Patents"), to which Abbott asserts that it is the exclusive licensee. Abbott claims that certain of IMT's products relating to pregnancy detection and ovulation prediction (now our products to the extent they are still sold) infringe the Pregnancy Test Patents. Abbott is seeking a finding that IMT and PBM infringe the Pregnancy Test Patents, an order permanently enjoining IMT and PBM from infringing the Pregnancy Test Patents, compensatory damages to be determined at trial, treble damages, costs, prejudgment and post-judgment interest on

Abbott's compensatory damages, attorneys' fees, and a recall of all of existing products found to infringe the Pregnancy Test Patents.

On August 5, 1998, the court denied Abbott's motion for a preliminary injunction. On March 31, 1999, the District Court granted a motion by IMT, PBM and PBM-Selfcare LLC (the "LLC"), a joint venture between PBM and IMT, which sought leave to amend the counterclaim against Abbott, asserting that Abbott is infringing U.S. Patent Nos. 5,559,041 (the "041 patent") and 5,728,587 (the "587 patent"), which are owned by the LLC. The amended counterclaims seek a declaration that Abbott infringes the LLC's patents, as well as permanent injunctive relief, money damages and attorneys' fees.

On November 5, 1998, Abbott filed suit in the United States District Court for the Northern District of Illinois seeking a declaratory judgment of non-infringement, unenforceability and invalidity of the 041 patent and the 587 patent. The Illinois court granted IMT's motion to transfer the aforementioned Illinois action to the District Court. IMT and PBM moved for summary judgment on their defense that the Abbott patents are invalid, and on September 29, 2000, the District Court granted partial summary judgment, holding that certain key claims in Abbott's patents are invalid as a matter of law. The court refused to grant summary judgment on Abbott's claims of infringement or IMT's remaining claims of invalidity.

On December 17, 2001, the District Court denied a motion by Abbott seeking reconsideration of the court's partial summary judgment in favor of IMT and PBM. Abbott renewed this motion on February 15, 2002. The District Court has not ruled on this motion. No trial date has been set at this time. In connection with our split-off from IMT, we assumed all obligations and liabilities of IMT arising out of this matter. We believe that we have strong defenses against Abbott's claims and we will continue to defend the case vigorously; however, a final ruling against IMT or us could have a material adverse impact on our sales, operations or financial performance.

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

Through several of our subsidiaries, we currently have several lawsuits pending against Pfizer, Inc. ("Pfizer") and certain other parties in the United States District Court for the District of New Jersey alleging, among other things, that Pfizer's e.p.t ® brand pregnancy tests infringe patents owned by us and seeking injunctive relief against further infringement, as well as damages. In the most recently filed of these cases, on December 19, 2002, the Court granted our request for a preliminary injunction against Pfizer, Inc., based on a finding that Pfizer's e.p.t.™ pregnancy tests, as manufactured by ABI, a subsidiary of Apogent, Inc., likely infringe U.S. Patent No. 6,352,862. The Court further denied Pfizer's request for a stay of the injunction pending appeal, which Pfizer has since filed. On March 12, 2003, the Court granted a further preliminary injunction against Pfizer, Inc., based on a finding that a new version of Pfizer's e.p.t. pregnancy test manufactured by Mizuho USA, Inc., a subsidiary of Mizuho Medy, Ltd., also likely infringes the same patent, as well as another patent owned by our subsidiary, Inverness Medical Switzerland GmbH. The Court's orders effectively preclude Pfizer from selling either of these versions of its e.p.t. pregnancy tests pending appeal and posting of a bond.

Princeton BioMeditech Corporation, a co-defendant in one the infringement suits against Pfizer and the subject of two other related infringement suits initiated by us, 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 and that we have attempted to monopolize the market for home pregnancy tests. We believe that we have strong defenses to all of the counterclaims and we are defending them vigorously. However, a final ruling against us could have a material adverse impact on our sales, operations or financial performance.

*Persona Litigation*

In April 2001, 68 consumers brought an action in London claiming defects in Unipath's Persona contraceptive device, negligence and breach of contract, all allegedly leading to unwanted pregnancies by the claimants in or prior to 1998. We believe that we have substantial defenses to the claims and we intend to vigorously defend this litigation. Formal documentary and other discovery permitted under the laws of the United Kingdom has only recently commenced and a trial is not expected until late 2003 or 2004. The case is insured, in the aggregate, by Unilever's product liability insurance up to 50 million British Pounds Sterling or more, depending on when the events giving rise to the consumers' suit occurred. As a result, we do not believe that an adverse ruling against us would have a material adverse impact on our sales, operations or financial performance.

*Other Pending and Potential Litigation*

Because of the nature of our business, we may be subject at any particular time to consumer product claims or various other lawsuits arising in the ordinary course of our business, including employment matters, and expect that this will continue to be the case in the future. 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, such as the suits against Pfizer and PBM discussed above. These suits can be expensive and results in counterclaims challenging the validity of our patents and other rights. We have filed at least twenty law suits around the world, including suits in the United States, Germany, France, Japan and Australia, against competitors whom we believe to be selling products that infringe our propriety rights.

## 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, 2002.

## 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 2002 and for the period November 23, 2001 through December 31, 2001. Our common stock began trading on AMEX on November 23, 2001, and prior to that date there was no established public trading market for shares of our common stock.

| | High | Low |
|---|---|---|
| **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 |
| **Fiscal 2001** | | |
| November 23 through December 31 | $19.35 | $15.47 |

The closing price of our common stock on March 28, 2003 was $19.26 and on that date there were 361 holders of record of our common stock.

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. The declaration 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. Our senior credit facility currently prohibits the payment of dividends.

### ITEM 6. SELECTED FINANCIAL DATA

The following tables provide selected financial data of our company as of and for each of the fiscal years in the five-year period ended December 31, 2002 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 financial data as of and for each of the fiscal years in the three-year period ended December 31, 2002 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 year ended December 31, 2002 included in our consolidated financial statements was audited by Ernst & Young LLP, independent auditors, while the information as of and for years ended December 31, 2001 and 2000 included in our consolidated financial statements was audited by Arthur Andersen LLP, independent public accountants. The selected financial data as of and for the year ended December 31, 1999 have been derived from our audited consolidated financial statements not included herein. The selected financial data as of and for the year ended December 31, 1998 have been derived from our unaudited consolidated financial statements which have been prepared on a basis consistent with our audited consolidated financial statements and, in the opinion of management, include all adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of our consolidated results of operations and financial position for that period.

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, 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 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. 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 late 2001 and IVC and the Wampole business during 2002 materially affected the comparability of the selected financial data. For a discussion of certain factors that materially affect the comparability of the selected financial data or cause the data reflected herein not to be indicative of our future results of operation or financial condition, see Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Certain Factors Affecting Future Results."

| | 2002 | 2001 | 2000 | 1999 | 1998 |
|---|---|---|---|---|---|
| | (in thousands, except per share data) | | | | |
| **Consolidated Statements of Operations:** | | | | | |
| Net revenue | $207,897 | $ 47,268 | $49,728 | $49,087 | $53,445 |
| Cost of sales | 112,508 | 26,149 | 26,235 | 27,823 | 27,168 |
| Gross profit | 95,389 | 21,119 | 23,493 | 21,264 | 26,277 |
| Operating expenses: | | | | | |
| Purchased in-process research and development | — | 6,980 | — | — | — |
| Research and development | 14,471 | 1,810 | 1,360 | 1,395 | 2,322 |
| Sales and marketing | 42,487 | 8,531 | 8,101 | 8,581 | 11,481 |
| General and administrative | 28,067 | 11,702 | 7,048 | 7,214 | 9,493 |
| Other expenses | 23,306 | 10,441 | — | — | 4,969 |
| Total operating expenses | 108,331 | 39,464 | 16,509 | 17,190 | 28,265 |
| Operating (loss) income | (12,942) | (18,345) | 6,984 | 4,074 | (1,988) |
| Interest and other expenses, net | (8,492) | (3,983) | (2,423) | (2,710) | (3,074) |
| (Loss) income from continuing operations before income taxes | (21,434) | (22,328) | 4,561 | 1,364 | (5,062) |
| Provision for income taxes | 2,683 | 2,134 | 1,781 | 1,007 | 1,115 |
| (Loss) income from continuing operations | $(24,117) | $(24,462) | $ 2,780 | $ 357 | $(6,177) |
| (Loss) income from continuing operations available to common shareholders(1) | $(36,065) | $(24,462) | $ 2,780 | $ 357 | $(6,177) |
| (Loss) income from continuing operations per common share—basic and diluted(1) | $ (3.63) | $ (3.84) | $ 0.59 | $ 0.11 | $ (2.53) |

(1) (Loss) income available to common shareholders and basic and diluted (loss) income per share are computed as described in Notes 1, 2(k) and 11 of the "Notes to Consolidated Financial Statements."

| | December 31, | | | | |
|---|---|---|---|---|---|
| | 2002 | 2001 | 2000 | 1999 | 1998 |
| | (in thousands) | | | | |
| **Balance Sheet Data:** | | | | | |
| Cash and cash equivalents | $ 30,668 | $ 52,024 | $ 3,071 | $ 661 | $ 1,111 |
| Working capital (deficit) | 28,209 | 19,555 | (6,464) | (4,060) | (1,986) |
| Total assets | 357,746 | 278,521 | 74,958 | 72,210 | 70,191 |
| Debt obligations | 104,614 | 78,124 | 12,830 | 19,076 | 23,163 |
| Redeemable convertible preferred stock | 9,051 | 51,894 | — | — | — |
| Total stockholders' equity | 162,904 | 89,614 | 41,812 | 34,953 | 28,932 |

**Effect of the Adoption of Statement of Financial Accounting Standard ("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 (loss) income from continuing operations data of our company, as if SFAS No. 142 was adopted for all periods presented.

| | Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2002 | 2001 | 2000 | 1999 | 1998 |
| | (in thousands, except per share data) | | | | |
| (Loss) income from continuing operations | $(24,117) | $(24,462) | $2,780 | $ 357 | $(6,177) |
| Add back: Goodwill amortization, net of tax | — | 398 | 398 | 557 | 2,052 |
| Adjusted (loss) income from continuing operations | $(24,117) | $(24,064) | $3,178 | $ 914 | $(4,125) |
| Adjusted (loss) income from continuing operations available to common shareholders(1) | $(36,065) | $(24,064) | $3,178 | $ 914 | $(4,125) |
| Adjusted (loss) income from continuing operations per common share—basic and diluted(1) | $ (3.63) | $ (3.78) | $ 0.67 | $0.27 | $ (1.69) |

(1) (Loss) income available to common shareholders and basic and diluted (loss) income per share are computed as described in Notes 1, 2(k) and 11 of the "Notes to Consolidated Financial Statements."

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

### Overview

We develop, manufacture and market consumer healthcare products, including self-test diagnostic products for the women's health market and vitamins and nutritional supplements. We also develop, manufacture and distribute a wide variety of professional diagnostic products for use by medical and laboratory professionals.

Our short-term business goal is to maintain profitability by enhancing market share and growing revenues, while simultaneously investing heavily in research and development of new products and technologies. The key drivers of our short-term success are (i) shipping quality products, (ii) manufacturing efficiently, (iii) maintaining strong customer relationships and (iv) successfully integrating the businesses that we acquired over the past year and may acquire during 2003.

Our long-term goal is to grow our profitability and market share by (i) successfully developing cost-effective, technologically advanced new products that give us a competitive advantage in our current and selected new markets, (ii) building strategic business combinations and alliances that enhance our already strong intellectual property portfolio and enable us to expand into our targeted new markets, (iii) defending our intellectual property from infringement by our competitors, and (iv) integrating any businesses and technologies that we acquire in the future.

In 2002, we recorded net revenue of $207.9 million, compared to $47.3 million in 2001. Since our split-off from IMT, our business has grown significantly through our acquisitions of the Unipath business in December 2001, IVC Industries (now operating as Inverness Medical Nutritionals Group or "IMN") in March 2002 and Wampole Laboratories in September 2002. The acquisition of the Unipath

business provides us with a large research and development facility in Bedford, England, which currently houses approximately 100 scientists and technicians, and significant intellectual property, which we believe gives us a technological competitive advantage. In addition, as evidenced by our research and development spending of $14.5 million in 2002, we are committed to bringing superior and technologically advanced products to the consumer and professional diagnostic markets. Our acquisition of IMN provides us with manufacturing facilities for the majority of our nutritional supplement products. Most recently, our acquisition of Wampole provides us with extensive distribution channels for our existing professional diagnostic products, as well as any new ones we will market in the future.

### Results of Operations

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

**Net Product Sales.** Net product sales increased by $154.2 million, or 326%, to $201.5 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 $88.3 million to our growth in net product sales, as it generated net product sales of $90.5 million in 2002, compared to only $2.1 million in 2001 (because it was acquired late 2001). IMN, with its comprehensive assortment of private label vitamins and nutritional supplements, and Wampole, with its extensive distribution channels for professional diagnostic products, contributed $44.4 million and $12.4 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 $5.1 million of the growth in net product sales in 2002, or a 12% 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.

In terms of product revenue growth by reporting segment, net product sales from our consumer products segment, which includes our consumer diagnostic products and our vitamins and nutritional supplements, increased by $131.9 million, or 359%, to $168.6 million in 2002 from $36.7 million in 2001. Net product sales from our professional diagnostic products segment increased by $22.3 million, or 210%, to $32.9 million in 2002 from $10.6 million in 2001. The growth in net product sales at both reporting segments was primarily the result of the acquisitions described above.

**License Revenue.** License revenue represents license and royalty fees from intellectual property license agreements with third-parties. 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 represents total gross profits less gross profits associated with license revenue. Gross profit from net product sales increased by $70.8 million, or 336%, to $91.9 million in 2002 from $21.1 million in 2001. Total gross margin from net product sales was 46% in 2002, compared to 45% in 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 $52.4 million, $7.0 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.

In terms of gross profit by reporting segment, gross profit from our consumer product sales increased by $61.4 million, or 407%, to $76.5 million in 2002 from $15.1 million in 2001. Gross margin from our consumer product sales was 45% 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 profit from our professional diagnostic product sales increased by $9.4 million, or 157%, to $15.4 million in 2002 from $6.0 million in 2001. Gross margin from our professional diagnostic product sales was 47% in 2002, compared to 57% in 2001, which decrease resulted from the change in the product mix.

**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. We currently expect to continue to invest heavily in research and development for the foreseeable future.

**Sales and Marketing Expense.** Sales and marketing expense increased by $34.0 million, or 400%, to $42.5 million in 2002 from $8.5 million in 2001. Of this increase, $25.5 million resulted from the addition of the Unipath business. The IMN and Wampole acquisitions accounted for $4.4 million and $1.9 million, respectively, of the increase in sales and marketing expense in 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 21% in 2002 from 18% in 2001. We expect sales and marketing expense on a gross basis to increase, as we bring new or improved products to the market.

**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 resulted primarily 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. We expect legal expenses to remain high as we continue to aggressively defend our intellectual property portfolio.

**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 the "Notes to Consolidated Financial Statements"). 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 the "Notes to Consolidated Financial Statement"). 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 the "Notes to Consolidated Financial Statement"). 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 includes interest charges, amortization of deferred financing costs and amortization of non-cash original issue discounts and discounts in the form of a beneficial conversion feature associated with our debt issuances. Interest expense increased by $7.4 million, or 370%, to $9.4 million in 2002 from $2.0 million in 2001. Of the total interest expense in 2002, $2.7 million represented the non-cash amortization of original issue discounts and beneficial conversion features. The increase in interest expense in 2002 resulted from various debt financings, which aggregated to $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. (See Notes 6(a) and (f) of the "Notes to Consolidated Financial Statement.")

**Other Income (Expense), Net.** Other income (expense), net, includes interest income and other income and expenses, which are primarily foreign exchange gains and losses. 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 recognized $975,000 in foreign exchange transaction gains, which included a one-time realized foreign exchange transaction gain of $2.6 million upon the settlement of an inter-company loan between two of our subsidiaries with different functional currencies. Excluding such one-time foreign exchange gain, we incurred foreign exchange losses of $1.6 million in 2002, compared to losses of $727,000 during 2001. The increase in foreign exchange transaction losses in 2002 resulted from the weakened US 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 US Dollar while its functional currency is the Euro. Also included in other income (expense), net, in 2002 is a charge of $1.2 million to mark to market an interest rate swap agreement because its hedge is deemed ineffective, as well as 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 ("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 13 of the "Notes to Consolidated Financial Statements.")

**(Loss) Income from Continuing Operations.** In 2002, we generated a loss from continuing operations of $24.1 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 $36.1 million, or $3.63 per basic and diluted share, in 2002. The loss in 2002 resulted from various factors as described above. In 2001, we generated a loss from continuing operations of $24.5 million, or $3.84 per basic and diluted share.

**Extraordinary Items.** In March 2002, we recorded a net extraordinary gain of $8.3 million related to the early retirement of certain of our subordinated promissory notes and the repurchase of the beneficial conversion feature associated with these subordinated promissory notes (see Note 6(g) of the "Notes to Consolidated Financial Statements"). In November 2002, we refinanced certain of our bank loans, and accordingly, recorded an extraordinary loss of $3.2 million to write-off the remaining unamortized deferred financing costs and original issue discount related to such bank loans (see Note 6(f) of the "Notes to Consolidated Financial Statements"). In 2001, we recorded an extraordinary loss of $327,000 which represented the write-off of the remaining unamortized deferred financing costs associated with a bank loan that IMT assumed and paid-off at the time of the split-off and merger in November 2001.

**Cumulative Effect of a Change in Accounting Principle.** On January 1, 2002, we adopted Statement of Financial Accounting Standard ("SFAS") No. 142, *Goodwill and Other Intangible Assets.* SFAS No. 142 requires annual 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 the "Notes to Consolidated Financial Statements"). There were no charges due to a change in accounting principle in 2001.

**Net (Loss) Income.** We generated a net loss of $31.1 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 $43.1 million, or $4.33 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 the "Notes to Consolidated Financial Statements" for the calculation of earnings per share.)

**Year Ended December 31, 2001 Compared to Year Ended December 31, 2000**

**Net Product Sales.** Net product sales decreased by $2.4 million, or 5%, to $47.3 million in 2001 from $49.7 million in 2000. The product sales decline was predominantly due to decreases in sales of certain of our nutritional supplement product lines, which are included in our consumer products business segment. The net sales of our nutritional supplements decreased by $6.5 million, or 36%, to

$11.4 million in 2001 compared to $17.9 million in 2000. Prior to our split-off from IMT, our marketing efforts had been limited due to the size and resources of our company, which, added to the effect of the competitive nature of this business, caused our nutritional supplements sales to decline. The decrease in product sales of nutritional supplements was partially offset by the increase in sales of our consumer diagnostic products, such as our home pregnancy detection and ovulation prediction tests, which are also included in our consumer products business segment. Net product sales of our consumer diagnostic products increased by $4.0 million, or 19%, to $25.2 million in 2001 from $21.2 million in 2000. Approximately $1.9 million of the consumer diagnostic product sales increase was contributed by the Unipath business that we acquired on December 20, 2001. Net sales of our professional diagnostics products decreased by $90,000, or 1%, to $10.6 million in 2001 from $10.7 million in 2000.

**Gross Profit.** Total gross profit decreased by $2.4 million, or 10%, to $21.1 million in 2001 from $23.5 million in 2000. Gross margin of net product sales was 45% in 2001, compared to 47% in 2000. The decrease in gross profit and gross margin primarily resulted from the decline in sales of our nutritional supplements, which are higher margin products compared to our other consumer products. Gross profit from our nutritional supplements product sales decreased by $3.8 million, or 45%, to $4.6 million in 2001 from $8.4 million in 2000. The decrease in gross profit from sales of our nutritional supplements was partially offset by the increase in gross profit from sales of our consumer diagnostic products. Gross profit from consumer diagnostic product sales increased by $1.7 million, or 19%, to $10.5 million in 2001 from $8.8 million in 2000. Gross profit from our professional diagnostics product sales decreased by $297,000, or 5%, to $6.0 million in 2001 from $6.3 million in 2000.

**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 ("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. We believe that many of the complex technical issues have been resolved; however, the technology does not have Food and Drug Administration approval. Therefore, the risk of not achieving commercialization is not only a developmental risk, but a regulatory risk as well. The work of a full project, which includes demonstrating feasibility, defining the project, design, development, verification and clinical testing, and regulatory submission and approval, will need to be completed prior to a launch of a product based on this technology. As these hurdles are crossed, new complexities are likely to arise. We initially anticipated that this IPRD Project would take one to one and a half years from the acquisition date to complete and the current estimate of the completion date remains unchanged. During the initial valuation of the project we estimated that it would cost approximately $2.7 million in additional research and development costs to complete this IPRD Project. Since then, we have incurred approximately $903,000 in research and development costs through December 31, 2002 and currently expect estimated costs to complete to be approximately $988,000. The reduction in estimated research and development costs to complete from the original estimate is due to our subsequent decision to change the outsourced prototype tooling and design work from a contractor in Europe to one in China. Based upon time and costs incurred, we estimate this IPRD Project to be approximately 95% complete as of December 31, 2002. We did not record any such charges in 2000.

**Research and Development Expense.** Research and development expense increased by $450,000, or 32%, to $1.8 million in 2001 from $1.4 million in 2000. Through 2001, most of our research and development expense was related to professional diagnostic products.

**Sales and Marketing Expense.** Sales and marketing expense increased by $430,000, or 5%, to $8.5 million in 2001 from $8.1 million in 2000. The increase resulted primarily from the addition of the Unipath business since its acquisition date. Sales and marketing expense as a percentage of net product sales increased to 18% in 2001 from 16% in 2000.

**General and Administrative Expense.** General and administrative expense increased by $4.7 million, or 67%, to $11.7 million in 2001 from $7.0 million in 2000. General and administrative expense as a percentage of net product sales increased to 25% in 2001 from 14% in 2000. Approximately $2.5 million of this increase resulted from more legal fees incurred in our active defenses of certain litigation matters in 2001. Other increases in general and administrative expenses relate to other professional fees, facilities costs due to a relocation of our United States office in 2001, salaries, insurance and the addition of the Unipath business.

**Stock-Based Compensation.** During 2001, we recorded a $10.4 million non-cash stock-based compensation expense which primarily resulted from the sale of our restricted stock to our chief executive officer and stock option grants to certain key executives because these securities were sold or granted below the market value of our stock on the measurement date (see Note 12(c) of the "Notes to Consolidated Financial Statements").

**Interest Expense.** Interest expense in 2001 remained consistent (a $68,000 decrease, or 3%) at $2.0 million compared to 2000.

**Other Expense, Net.** Other expense, net, includes interest income and other income and expenses. Interest income increased by $358,000 to $385,000 in 2001 from $27,000 in 2000. The increase in interest income resulted from higher average cash balances from contributions by IMT in 2001. A significant portion of other income and expense generally represents foreign currency exchange gains and losses. In 2001, we recognized $727,000 in foreign exchange transaction losses as compared to losses of $389,000 in 2000. In 2001, we also settled a lawsuit for which we recorded a loss of $1.7 million which was included in other expense.

**Provision for Income Taxes.** In 2001, we recorded provisions of $2.1 million for income taxes compared to $1.8 million in 2000. The increase was primarily due to the write-off of certain deferred tax assets that we did not believe would provide us with future tax benefits as a result of the split-off and merger with IMT and Johnson & Johnson in November 2001 (see Note 13 of the "Notes to Consolidated Financial Statements").

**Loss (Income) from Continuing Operations.** Loss from continuing operations was $24.5 million, or $3.84 per basic and diluted common share, for 2001, compared to income from continuing operations of $2.8 million, or $0.59 per basic and diluted common share, for 2000. The loss in 2001 resulted from the various factors described above.

**Income (Loss) from Discontinued Operations.** In 2001, we had income from discontinued operations of $58,000, compared to a loss from discontinued operations of $598,000 in 2000. The discontinued operations represented the diabetes related segments that were acquired by Johnson & Johnson on November 21, 2001 (see Notes 1 and 15(d) of the "Notes to Consolidated Financial Statements").

**Extraordinary Loss on Early Extinguishment of Debt.** The amount charged to extraordinary loss in 2001 represented the write-off of the remaining unamortized deferred financing costs related to a third-party debt IMT assumed and paid-off at the split-off and merger.

Net (Loss) Income. Net loss was $24.7 million, or $3.88 per basic and diluted common share, for 2001, compared to net income of $2.2 million, or $0.46 per basic and diluted common share, for 2000 (see Notes 1, 2(k) and 11 of the "Notes to Consolidated Financial Statements"). The loss in 2001 resulted from the various factors described above.

## Supplementary Quarterly Financial Information

Selected quarterly financial data for the years 2002 and 2001 are summarized below:

| | 2002 | | | | 2001 | | | |
|---|---|---|---|---|---|---|---|---|
| | First Quarter | Second Quarter | Third Quarter | Fourth Quarter | First Quarter | Second Quarter | Third Quarter | Fourth Quarter |
| | (2) | (3) | | (4) | (5) | (5) | (5) | (5) & (6) |
| | (in thousands, except per share data) | | | | | | | |
| Net revenue | $ 37,247 | $51,709 | $53,947 | $64,994 | $11,485 | $11,647 | $11,159 | $12,977 |
| Gross profit | 19,007 | 21,402 | 24,650 | 30,331 | 5,505 | 5,860 | 5,095 | 4,660 |
| (Loss) income from continuing operations | (27,648) | (2,689) | 1,141 | 5,079 | 710 | 151 | (288) | (25,035) |
| Net (loss) income | (31,457) | (2,689) | 1,141 | 1,869 | 129 | 891 | 153 | (25,907) |
| (Loss) income from continuing operations available to common stockholders(1) | (29,177) | (4,962) | (6,724) | 4,798 | 710 | 151 | (288) | (25,035) |
| **(Loss) income per common share from continuing operations(1):** | | | | | | | | |
| Basic | $ (4.12) | $ (0.58) | $ (0.65) | $ 0.35 | $ 0.12 | $ 0.02 | $ (0.04) | $ (3.86) |
| Diluted | $ (4.12) | $ (0.58) | $ (0.65) | $ 0.31 | $ 0.12 | $ 0.02 | $ (0.04) | $ (3.86) |

(1) (Loss) income from continuing operations available to common shareholders and basic and diluted (loss) income per share are computed as consistent with the annual per share calculations described in Notes 1, 2(k) and 11 of the "Notes to Consolidated Financial Statements."

(2) Included in the loss from continuing operations in the first quarter of 2002 are an impairment charge of $12.7 million representing a write-off of certain intangible assets and 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. Net loss for the first quarter of 2002 also includes an extraordinary gain of $8.3 million relating to the repurchase of a beneficial conversion feature associated with debt that was early extinguished and a $12.1 million charge for the cumulative effect of an accounting change. The loss from continuing operations of $27.6 million is lower by $166,000, or $0.02 per basic and diluted share, compared to the amount reported in our quarterly report on Form 10-Q, as amended, for the three months ended March 31, 2002, because of a reclassification from interest expense to extraordinary items.

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

(4) Included in income from continuing operations and net income in the fourth quarter of 2002 is a one-time foreign exchange gain of $2.6 million on the settlement of a portion of an inter-company loan between two of our subsidiaries. In addition, net income in the fourth quarter of 2002 includes a $3.2 million extraordinary loss due to an early extinguishment of debt.

(5) In each of the quarters of 2001, net income (loss) includes (loss) income from discontinued operations of $(581,000), $739,000, $441,000 and $(545,000), respectively, relating to the split-off and merger transaction with IMT and Johnson & Johnson.

(6) Included in the loss from continuing operations in the fourth quarter of 2001 are (i) a charge of $7.0 million to write-off the value allocated to an acquired in-process research and development project, (ii) a non-cash stock-based compensation charge of $10.4 million relating to stock option grants made under an executive bonus plan adopted in connection with our split-off from IMT, and (iii) a litigation settlement charge of $1.7 million. In addition to the loss from discontinued operations, as described in footnote (5) above, net loss for the fourth quarter of 2001 includes a $327,000 extraordinary loss due to an early extinguishment of debt.

## Liquidity and Capital Resources

Based upon our working capital position, current operating plans and business conditions, we believe that our existing capital resources and credit facilities will be adequate to fund our operations, including our current outstanding debt and other commitments, as discussed below, for at least the next 12 months. This may be adversely impacted by unforeseen costs associated with integrating the

proposed merger with Ostex International, Inc. and our ability to refinance our subsidiary IMN's loans under the credit agreement with Congress Financial Corporation, as discussed below. We cannot be certain, however, that our underlying assumed levels of revenues and expenses will be realized. In addition, we intend to continue to expand our research and development efforts related to the substantial intellectual property portfolio acquired in connection with our Unipath and Wampole acquisitions, as well as the intellectual property we may acquire in connection with our proposed acquisition of Ostex. We may also choose to further expand our research and development of, and may pursue the acquisition of, new products and technologies, through licensing arrangements, business acquisitions, or otherwise. If we decide to pursue such activities or if our operating results fail to meet our expectations, we could be required to seek additional funding through public or private financings or other arrangements. In such event, adequate funds may not be available when needed, or, if available, may not be on acceptable terms, which could have a negative effect on our business and results of operations. In addition, if we raise additional funds by issuing equity or convertible securities, dilution to then existing stockholders may result.

*Changes in Cash Position*

As of December 31, 2002, we had cash and cash equivalents of $30.7 million, a $21.4 million decrease, or 41%, from December 31, 2001. We have historically funded our business through operating cash flows, proceeds from borrowings and the issuance of equity securities, as well as contributions from IMT and affiliated companies of IMT prior to November 2001. We generated $11.7 million in cash from our operating activities in 2002, which was due to an income, adjusted for non-cash items, of $14.1 million and a net working capital increase, excluding cash, of $2.4 million. During 2002, we also generated cash of $56.3 million from financing activities, which primarily involved bank borrowings of $53.0 million in November 2002, borrowings from private investors totaling $35.0 million in September 2002, our follow-on public offering, which raised $34.3 million in May 2002, net of underwriter's discounts and commissions and other offering costs, proceeds of $1.0 million from the exercises of certain common stock options and warrants and our issuance of $20.6 million of preferred stock to private investors in March 2002.

During 2002, we used cash of $86.6 million for our investing activities. Our primary investing activities consisted of $70.6 million and $7.1 million paid for the acquisitions of Wampole and IMN, respectively, $2.8 million paid for restructuring and additional costs related to the acquisition of the Unipath business, $1.0 million in loans to Ostex (as discussed below), and $6.1 million in capital expenditures, offset by $1.5 million in proceeds from the sale of property and equipment. We also utilized a portion of the proceeds we received from our debt and equity securities issuances to make principal prepayments and repayments of $20.0 million on certain subordinated promissory notes in March 2002 and $63.6 million on the term loans with The Royal Bank of Scotland plc and to pay financing costs of $4.0 million. Working capital was $28.2 million as of December 31, 2002, compared to $19.6 million as of December 31, 2001.

*Investing Activities*

On September 6, 2002, we entered into an agreement and plan of merger with Ostex, pursuant to which we intend to acquire Ostex. Ostex develops and commercializes osteoporosis diagnostic products. We expect this merger to provide us with intellectual property rights in the field of osteoporosis testing, synergies through Ostex's existing and in-process intellectual property and the elimination of redundant positions, the ability to increase sales of Ostex's existing products through the use of our marketing and distribution channels and the opportunity for significant cost savings. The pending acquisition of Ostex is subject to several closing conditions, including approval of the merger agreement governing the acquisition by Ostex's shareholders and our receipt of any necessary consents with respect to the transactions contemplated by the merger agreement required under any of our material loan

agreements. On February 18, 2003, in order to increase the likelihood that we would obtain the consent to the merger from our senior lender, as required under our material loan agreements, the parties amended the merger agreement to reduce the consideration we will pay to acquire Ostex. Under the merger agreement, as amended, the aggregate number of shares of our common stock to be issued in the merger for Ostex's outstanding shares and to be reserved for the options and warrants to be assumed by us is 1.9 million shares. Under the amended merger agreement, at the effective time of the merger, each outstanding share of Ostex common stock shall be converted into the right to receive a number of shares of our common stock equal to a conversion ratio that is to be calculated by dividing 1.9 million by the sum of (1) the total number of shares of Ostex common stock outstanding immediately prior to the effective time of the merger, and (2) the total number of shares of Ostex common stock subject to outstanding stock options and warrants that we were to assume in the merger. The shares of Ostex common stock subject to options and warrants to be assumed by us will convert at the same ratio. Also as part of the merger transaction, we have agreed to lend up to $2.0 million to Ostex to support their operations prior to the effective time of the merger. To date, we have made loans aggregating $1.6 million to Ostex. The merger remains subject to approval by the holders of two thirds of Ostex's outstanding voting stock, the receipt of third-party consents, including the consent of our senior lender, and certain other customary closing conditions, so there can be no assurance that our acquisition of Ostex will occur. If and when we complete the acquisition of Ostex, we will be required to issue a significant number of shares of our common stock, which will likely dilute our earnings per share.

On September 20, 2002, we significantly expanded our professional diagnostics business with our acquisition of the Wampole Laboratories division of MedPointe Inc. Wampole is a leader in enzyme linked immuno sorbent assay ("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, physician's offices and clinics through an extensive U.S. distribution network, and compliment our existing professional diagnostic products lines and their international distribution networks. The acquisition of Wampole also provides us with significant new intellectual property. The aggregate purchase price of Wampole was approximately $71.5 million, which consisted of $70.0 million in cash and approximately $1.5 million in estimated direct acquisition costs. The acquisition was funded with a portion of our existing cash and the proceeds from the issuance of $35.0 million in subordinated debt, the terms of which are discussed below.

On March 19, 2002, we acquired IVC Industries, Inc. (now operating as Inverness Medical Nutritionals Group or "IMN"), a manufacturer and distributor of vitamins and nutritional supplements primarily in the United States. With the addition of IMN, we were able to consolidate certain of our vitamin and nutritional supplement manufacturing at IMN and discontinue most of our outsourced manufacturing arrangements. The aggregate purchase price of IMN was $27.3 million, which consisted of $5.6 million in cash, representing $2.50 for each outstanding share of IMN's common stock, fully-vested stock options to purchase an aggregate of 115,744 shares of our common stock, which options had an aggregate fair value of $1.3 million, approximately $1.6 million in costs to exit certain activities of IMN, primarily severance costs, $17.4 million in assumed debt, including capital leases, and approximately $1.4 million in direct acquisition costs. We funded the acquisition of IMN with our existing cash.

*Financing Activities*

On November 14, 2002, our company and certain of our subsidiaries entered into a senior credit agreement with a group of banks, including General Electric Capital Corporation, Keybank National Association and the Royal Bank of Scotland Plc, for credit facilities in the aggregate amount of up to $55.0 million. The senior credit agreement consists of a U.S. term loan of $20.0 million, a European term loan of $10.0 million and a European revolving line of credit of up to $25.0 million. Aggregate

initial borrowings amounted to $30.0 million under the term loans and $22.96 under the revolving line of credit upon the execution of the senior credit agreement, which amounts were also outstanding as of December 31, 2002. Principal repayments under the U.S. term loan are to be made in eleven equal quarterly installments of $1.25 million starting on April 30, 2003 through October 31, 2005 with a final installment of $6.25 million due in November 2005. Principal repayments under the European term loan are to be made in fourteen equal quarterly installments of $25,000 starting on January 31, 2003 through April 30, 2006 with a final installment of $9.65 million due in May 2006. We may also choose to prepay all or part of the term loans provided that we prepay at least $1.0 million or a multiple thereof. We may repay our borrowings under the revolving line of credit at any time but in no event later than November 14, 2005. We must make mandatory prepayments on the loans under the senior credit agreement if we meet certain cash flow thresholds, collect certain insurance proceeds in excess of certain thresholds, issue equity securities on or after November 14, 2003 or sell assets not in the ordinary course of our business. Borrowings under the term loans and the revolving line of credit bear interest at either (i) the London Interbank Offered Rate ("LIBOR"), as defined in the credit agreement, plus applicable margins or, at our option, (ii) a floating Index Rate, as defined in the credit agreement, plus applicable margins. Applicable margins, depending on the type of loan, can range from 1.25% to 3.75% and are subject to quarterly adjustments based on our total leverage ratio, as defined in the credit agreement. At December 31, 2002, the interest rates of the U.S. term loan, the European term loan and the revolving line of credit were 6.25%, 6.75% and 6.25%, respectively. Borrowings under this senior credit agreement are secured by the stock of certain of our U.S. and European subsidiaries, a significant portion of our intellectual property rights and the assets of our business in the U.S. and Europe, excluding those assets of IMN, Orgenics Ltd., our Israeli subsidiary, Orgenics' subsidiaries and Unipath Scandinavia AB, our Swedish subsidiary. Under this senior credit agreement, we must comply with various financial and nonfinancial covenants. The primary financial covenants pertain to, among other things, fixed charge coverage ratio, capital expenditure, various leverage ratios, EBITDA and minimum cash requirement. In addition, the senior credit agreement currently prohibits us from paying dividends. As of December 31, 2002, we were in compliance with the covenants. Failure to comply with these covenants may have a material adverse impact on our financial condition. Upon receipt of the proceeds from the loans under the senior credit agreement, we used $44.1 million thereof to prepay the outstanding principal balance and any accrued and unpaid interest on the term loans and line of credit under a series of credit agreements with the Royal Bank of Scotland Plc and related entities, as described below.

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 (i) a 10% subordinated promissory note in the principal amount of $50,000 and (ii) 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 cash commissions and an expense allowance totaling $970,000 and 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 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. Both the 9% subordinated notes and the 3% convertible notes mature on September 20, 2008, subject to acceleration in certain circumstances, and we may prepay the 9% subordinated notes at any time, subject to certain prepayment penalties and the consent of our senior lenders. If we repay the 9% subordinated notes and the 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 per share. 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 per share 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.

In connection with the IMN acquisition, we assumed all of IMN's long-term debt. As of December 31, 2002, IMN had a total outstanding debt balance of $17.3 million, of which $11.7 million related to a credit agreement with Congress Financial Corporation, a subsidiary of First Union Corporation, and $5.6 million related to various notes payable and capital leases. Under the credit agreement with Congress, 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. At December 31, 2002, the interest rates on the loans with Congress ranged from 4.65% to 5.75%. The notes are collateralized by substantially all of IMN's assets. The credit agreement with Congress 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, 2002, IMN was in compliance with such requirements and restrictions. The loans with Congress are set to mature on October 16, 2003 and because we are restricted in funding IMN under our senior credit agreement, our current intention is to refinance the Congress loans with a new arrangement when those become due. However, a new financing arrangement may not be available when needed, or, if available, may not be on acceptable terms, which could have a negative effect on our business and results of operations. IMN's other notes payable and capital leases mature on various dates through July 2008.

On March 6, 2002, we prepaid our then outstanding subordinated promissory notes, which had an aggregate principal amount of $20.0 million, and related accrued interest of $568,000 using the proceeds from the issuance of Series A Redeemable Convertible Preferred Stock, as discussed below.

On December 20, 2001, one of our wholly-owned subsidiaries entered into a series of credit agreements with the Royal Bank of Scotland Plc and related entities for credit facilities in the aggregate amount of $65.0 million, as amended. The credit agreements with the Royal Bank of Scotland consisted of various term loans initially aggregating $62.5 million, of which $10.0 million were

denominated in Japanese Yen and $10.0 million represented a junior loan, and a $2.5 million multicurrency revolving line of credit, as amended. The proceeds of these term loans were used to finance a portion of the cash used to acquire the Unipath business. The per annum interest rate on the loans was the London Interbank Offered Rate ("LIBOR") plus a spread from 1.50% to 3.50% (and an additional 2.00% in case of default), depending on the type of loan (senior or junior) and the interest period. In addition, interest at 4.00% per annum was capitalized on the junior loan. On November 14, 2002, we refinanced the outstanding principal balances and any unpaid interest on the term loans and line of credit under the credit agreements with the Royal Bank of Scotland with proceeds from the new senior credit agreement entered into with General Electric Capital Corporation and other banks on that date, as discussed above.

During 1999, our subsidiary CDIL financed the purchase of one of the buildings that houses its manufacturing activities through a mortgage loan with the seller. The outstanding balance of the CDIL Mortgage was $144,000 as of December 31, 2002. The mortgage loan bears interest at 6% and is payable semiannually through 2003.

As of December 31, 2002, our subsidiary Orgenics had bank debt balances totaling $377,000. Orgenics' bank debt is collateralized by certain of Orgenics' assets. Orgenics' notes bear interest at rates ranging from 3.3% to 13% and are payable on various dates through 2004.

In May 2002, we sold an aggregate of 1.6 million shares of our common stock in a follow-on public offering. Total net proceeds from the follow-on offering were approximately $34.3 million after deducting underwriter's commissions and other offering costs totaling $2.5 million.

In March 2002, we sold to private investors 531,913 shares of our Series A Redeemable Convertible Preferred Stock at $39.01 per share for gross proceeds of $20.75 million for purposes of prepaying the then outstanding $20.0 million subordinated promissory notes and related accrued and unpaid interest. The terms of these shares of Series A Preferred Stock are the same as the 1,995,000 shares of Series A Preferred Stock issued in December 2001. Each share of Series A Preferred Stock accrues dividends on a quarterly basis at $2.10 per annum, but only on those days when the closing price of our common stock is below $15. During 2002, we recorded $326,000 in dividends. Dividends accrued are payable only if declared by the board of directors. Until December 31, 2003, accrued dividends, if any, must be paid in our common stock. The number of shares of common stock to be issued in payment of any accrued dividends is equal to such number as is determined by dividing the aggregate amount of the accrued dividend then payable by the greater of (i) $15 or (ii) the average market price during the 30 trading day period immediately preceding the date such dividend is declared. Thereafter, we have the option to pay dividends in cash or common stock. In addition, our senior credit agreement currently prohibits us from paying dividends. The number of shares of common stock to be issued upon any voluntary conversion of one share of Series A Preferred Stock is equal to such number as is determined by dividing $30 by the conversion price in effect at the time of conversion. As of December 31, 2002, the conversion price was $15, subject to adjustment. Accordingly, each share of Series A Preferred Stock is currently convertible into two shares of common stock. The effective purchase price for the shares of common stock underlying the Series A Preferred Stock issued in March 2002 represented a $2.70 (or 12%) discount to the fair value of our common stock on the issuance date. Starting on December 20, 2003, we may convert the Series A Preferred Stock into common stock in the event that the average closing price of our common stock exceeds $20 for any consecutive 30 trading day period. The Series A Preferred Stock may be redeemed upon a vote by the holders of at least two-thirds of the outstanding Series A Preferred Stock on or after June 30, 2011. The redemption price per share of Series A Preferred Stock will be equal to $30 plus a premium calculated at 5% per annum from the date of issuance. During 2002, 1,742,347 shares of the Series A Preferred Stock were converted into 3,484,694 shares of our company's common stock. As of December 31, 2002, there were 323,060 shares of Series A Preferred Stock outstanding.

*Income Taxes*

As of December 31, 2002, we had approximately $21.1 million and $19.1 million of domestic and foreign net operating loss carryforwards, respectively, which either expire on various dates through 2022 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 tax 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 the 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.

*Contractual Obligations*

The following table summarizes our principal contractual obligations as of December 31, 2002 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** | **2003** | **2004 - 2005** | **2006 - 2007** | **Thereafter** |
| | | | (in thousands) | | |
| Long-term debt obligations(1) | $102,877 | $17,200 | $40,577 | $10,100 | $35,000 |
| Capital lease obligations(2) | 3,572 | 865 | 1,196 | 1,170 | 341 |
| Operating lease obligations(3) | 55,637 | 4,634 | 8,204 | 7,142 | 35,657 |
| Purchase obligations(4) | 2,423 | 2,423 | — | — | — |
| Total | $164,509 | $25,122 | $49,977 | $18,412 | $70,998 |

(1) See description of various financing arrangements in this section and Note 6 to the "Notes to Consolidated Financial Statements."

(2) See Note 7 to the "Notes to Consolidated Financial Statements."

(3) See Note 10(a) to the "Notes to Consolidated Financial Statements."

(4) Purchase obligations are primarily comprised of firm capital expenditure commitments to support the production of certain of our improved products.

## Critical Accounting Policies

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

*Revenue Recognition*

We recognize revenue in accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 101 and its related amendments (collectively, "SAB No. 101"). SAB No. 101 requires that four basic criteria be met before revenue can be recognized: (1) persuasive evidence of an arrangement

exists; (2) delivery has occurred or services rendered; (3) the fee is fixed and determinable; and (4) collection is reasonably assured.

The majority of our revenues are derived from product sales. We recognize revenue upon 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.

Since our acquisitions of the Unipath business in December 2001 and Wampole in September 2002, 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 are calculated based on the licensees' sales are recognized upon receipt of the license or royalty payments because we would not be able to determine such fees until such time.

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

Sales arrangements with customers for our consumer products generally require us to accept product returns. From time to time, we also enter into sales incentive arrangements with our customers, which generally reduce the sale prices of our products. Against product revenue recognized in any reporting period, we must establish allowances for potential future product returns and claims resulting from our sales incentive arrangements. Calculation of these allowances requires significant judgments and estimates. When evaluating the adequacy of the sales returns and other allowances, our management analyzes historical returns, current economic trends, and changes in customer demand and acceptance of our products. Material differences in the amount and timing of our product revenue for any reporting period may result if changes in conditions arise that would require management to make different judgments or utilize different estimates. Our provision for sales returns and other allowances related to sales incentive arrangements amounted to approximately $43.9 million in 2002 and $4.8 million in 2001. The increase primarily resulted from the addition of the Unipath business and IMN.

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 $37.3 million and $21.6 million, net of an allowance for doubtful accounts of $871,000 and $858,000 as of December 31, 2002 and 2001, 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 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 $37.2 million, which is net of a provision of $1.3 million, as of December 31, 2002.

*Valuation of Goodwill and Other Long-Lived and Intangible Assets*

Our long-lived assets include property, plant and equipment, goodwill and other intangible assets. As of December 31, 2002, the balances of property, plant and equipment, goodwill and other intangible assets, net of accumulated depreciation and amortization, were $45.8 million, $108.9 million and $79.9 million, respectively. 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 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, when indicators of impairment are present. Effective January 1, 2002, 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, such loss would be charged to expense in the period we identify the impairment. In addition, if our review of the carrying values of the long-lived tangible and intangible assets 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

As of January 1, 2002, we adopted SFAS No. 142 and obtained an independent review on the carrying value of our existing goodwill in accordance with this statement which provides specific guidance for determining and measuring impairment of goodwill. Based upon the results of the review, we recorded an impairment charge of $12.1 million, representing the remaining goodwill related to our reporting unit that comprises the nutritional supplement lines we acquired in 1997. This amount represented the excess of the carrying value over the fair value of such asset. The fair value was determined using a combination of the income approach and the market approach of valuing a business. The income approach valued the business by discounting projected future cash flows and the market approach valued the security underlying the business by comparing it to those of similar businesses. The most significant facts and circumstances that led to the conclusion of this impairment were (a) future cash flows from these nutritional supplement lines are expected to be reduced, (b) selling, general and administrative expenses relating to these nutritional supplement lines are forecasted to increase as a percentage of sales, and (c) this nutritional supplements business is experiencing a larger percentage decline in revenues than most of the comparable businesses of other companies. Because future cash flows and operating results used in the independent review are based on management's projections and assumptions, future events can cause actual results to differ from those projections. In such event, the full impairment charge of $12.1 million taken during the first quarter of 2002 may not be justified.

At December 31, 2002, we had goodwill balances related to our consumer diagnostics and professional diagnostics reporting units of $66.5 million and $42.4 million, respectively. As such, we performed an impairment review on the carrying values of such goodwill. Based on the discounted projected future cash flows approach, we do not believe that the goodwill related to our consumer diagnostics and professional diagnostics reporting units were impaired as of December 31, 2002. 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, 2002, which could lead to significant impairment charges of goodwill in the future.

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.

Because the independent appraisal of the fair value of the reporting unit underlying our nutritional supplements business indicated an impairment of goodwill related to that reporting unit, as discussed above, we proceeded to also obtain an independent impairment review of the carrying value assigned to related trademarks and brand names. The results of this review indicated an impairment of the carrying value of such trademarks and brand names because the full carrying amount of these intangible assets was not expected to be recoverable and exceeded its fair value. The full carrying amount of these intangible assets was not recoverable because it exceeded the sum of the undiscounted cash flows expected to result from the use and eventual disposition of these assets. The fair value of these intangible assets was determined using a combination of the discounted cash flow approach and the relief from royalty approach, the latter of which valued the trademarks as if they were licensed from a third party. Based on these results, we recorded another impairment charge of $12.7 million to write-off a portion of the carrying value of these trademarks and brand names during the first quarter of 2002. The remaining carrying value of these intangible assets was $4.1 million at December 31, 2002, which is being amortized over the assets average remaining useful lives of 19 years. The impairment was measured partly based on a projected discounted cash flow method using a discount rate determined by our management to be commensurate with the risk inherent in our current business model. Although we believe that the remaining carrying value of our long-lived tangible and intangible assets was realizable as of December 31, 2002, future events could cause us to conclude otherwise.

*Accounting for Income Taxes*

As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves us estimating our actual current tax exposure and assessing temporary differences resulting from differing treatment of items, such as reserves and accruals and lives assigned to long-lived and intangible assets, for tax and accounting purposes. These differences result in deferred tax assets and liabilities. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within our tax provision.

Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have recorded a valuation allowance of $28.2 million as of December 31, 2002 due to uncertainties related to the future benefits, if any, from our deferred tax assets primarily related 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 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." We do not accrue for potential losses on legal proceedings where our company is the defendant when we are not able to quantify our potential liability, if any, due to uncertainty as to the nature, extent and validity of the claims against us, uncertainty as to the nature and extent of the damages or other relief sought by the plaintiff and the complexity of the issues involved. Our potential liability, if any, in a particular case may become quantifiable as the case progresses, in which case we will begin accruing for the expected loss.

In addition, in Item 3 of this report, we have reported on certain legal proceedings as to which we do not believe a final ruling against us could have a material adverse impact on our financial position and operations. To the extent that unanticipated facts or circumstances arise that cause us to change this assessment with respect to any matter, our future results of operations and financial position could be materially affected.

Recently Issued Accounting Standards

In June 2001, the Financial Accounting Standards Board ("FASB") issued Statement of Financial Accounting Standard ("SFAS") No. 143, *Accounting for Asset Retirement Obligations*. This statement addresses the accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the related asset retirement costs, in particular legal obligations associated with such retirement that result from the acquisition, construction, development and (or) the normal operation of a long-lived asset, except for certain obligations of lessees. We adopted this statement on January 1, 2003, as required. However, the adoption of this statement did not have a material impact on our financial position, results of operations or cash flows.

In November 2001, the Emerging Issues Task Force ("EITF") issued EITF Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer or a Reseller of the Vendor's Products*. EITF Issue No. 01-9 establishes accounting and reporting standards for vendor consideration to any purchasers of the vendor's products at any point along the distribution chain, regardless of whether the purchaser receiving the consideration is a direct customer. We offer certain sales incentives that fall within the scope of EITF Issue No. 01-9, such as slotting fees and cooperative advertising, to some of our customers. We adopted the provisions of this consensus in 2002, the effect of which were reductions to net product sales in the amounts of $2.4 million and $2.5 million during 2001 and 2000, respectively, because of reclassifications from sales and marketing expenses for comparative purposes. These and certain other reclassifications impacting net product sales and cost of sales had no effect on our loss or income from continuing operations or net loss or income in the respective years.

In April 2002, the FASB issued SFAS No. 145, *Rescission of FASB Statements No. 4, 44 and 64 Amendment of FASB Statement No. 13 and Technical Corrections,* which addresses the reporting of gains and losses resulting from the extinguishment of debt, accounting for sale-leaseback transactions and rescinds or amends other existing authoritative pronouncements. SFAS No. 145 requires that any gain or loss on the extinguishment of debt that does not meet the criteria of Accounting Principles Board ("APB") Opinion No. 30 for classification as an extraordinary item shall not be classified as extraordinary and shall be included in earnings from continuing operations. We adopted the provisions of this statement on January 1, 2003, as required. As a result, any gains and losses from early

extinguishment of debt in the future will be included in earnings from continuing operations and all periods prior to January 1, 2003 will be restated accordingly. Consequently, the restatement of prior period losses upon the adoption of this statement will reduce our loss from continuing operations to $19.0 million, or $3.11 per basic and diluted share, in 2002 and increase our loss from continuing operations to $24.8 million, or $3.89 per basic and diluted share, in 2001.

In June 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities,* which addresses the recognition, measurement and reporting of costs associated with exit and disposal activities, including restructuring activities. This statement supersedes the guidance set forth in EITF Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring).* SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity only be recognized when the liability is incurred, while under the previous guidance of EITF Issue No. 94-3, such liability would have been recognized at the date of an entity's commitment to an exit plan. This statement also establishes that fair value should be used for initial measurement of the liability. However, this statement does not apply to costs associated with exit activities that involve an entity newly acquired in a business combination. We are required to apply the guidance of SFAS No. 146 with respect to exit or disposal activities initiated after December 31, 2002. Under our current operating plans, we do not expect the adoption of this statement to have a material impact on our financial position, results of operations or cash flows.

In November 2002, the FASB issued Interpretation ("FIN") No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, which will significantly change current practice in the accounting for, and disclosure of, guarantees. FIN No. 45 requires that a guarantor recognize, at the inception of certain types of guarantees, a liability of the obligation undertaken in issuing the guarantee at fair value. The interpretation also requires significant new disclosures in the financial statements of the guarantor about its obligations under certain guarantees. We are required to apply the disclosure provisions of FIN No. 45 in our financial statements as of December 31, 2002. The accounting provisions of FIN No. 45 are applicable for guarantees issued or modified after December 31, 2002. The disclosure requirements of FIN No. 45 did not have a material effect on our financial statements and we do not expect the accounting provisions of this interpretation to have a material impact on our financial position, results of operations or cash flows.

In December 2002, the FASB issued SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure*. This statement amends SFAS No. 123, *Accounting for Stock-Based Compensation,* to provide alternative methods of transition to SFAS No. 123's fair value method of accounting for stock-based employee compensation. SFAS No. 148 also amends the disclosure provisions of SFAS No. 123 and APB Opinion No. 28, *Interim Financial Reporting*, to require expanded disclosure of the effects of a company's accounting policy for stock-based employee compensation. The statement does not require companies to account for employee stock options using the fair value method. We adopted the disclosure provisions of SFAS No. 148 as of December 31, 2002, as required. However, we will continue to account for employee stock options using the intrinsic value method under APB Opinion No. 25, *Accounting for Stock Issued to Employees*, as permitted.

**Certain Factors Affecting Future Results**

There are various risks, including those described below, which may materially impact your investment in our company or may in the future, and, in some cases already do, materially affect us and our business, financial condition and results of operations. You should consider carefully these factors 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 on pages 2 and 53 of this report.

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

As of December 31, 2002, we had approximately $106.4 million of outstanding indebtedness under our credit facilities and other debt-related instruments. This substantial level of debt affects our future operations in several important ways, including the following:

- our ability to obtain additional financing may be impaired;
- our flexibility to adjust to market conditions is limited, leaving us vulnerable in a downturn in general economic conditions or in our business and less able to plan for, or react to, changes in our business and the industries in which we operate;
- we may need to use a large portion of our cash flow from operations to pay principal and interest on our indebtedness, which would reduce the amount of cash available to finance our operations and other business activities and may require us, in order to meet our debt service obligations, to delay or reduce capital expenditures or the introduction of new products and/or forego business opportunities including acquisitions, research and development projects or product design enhancements; and
- we may be at a competitive disadvantage compared to our competitors that have less debt.

Furthermore, we cannot assure you that our cash flow from operations and capital resources will be sufficient to pay our indebtedness. If our cash flow and capital resources prove inadequate, we could face substantial liquidity problems and might be required to dispose of material assets or operations, restructure or refinance our debt or seek additional equity capital.

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

- incur additional indebtedness;
- acquire other businesses;
- make investments;
- make loans to or extend credit for the benefit of third parties or our subsidiaries;
- raise additional capital;
- make capital or finance lease expenditures; and
- dispose of or encumber assets.

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

**Our credit facilities contain certain financial covenants 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 December 31, 2002, we had approximately $64.7 million of outstanding indebtedness under our various credit facilities, substantially all of which was owed to General Electric Capital Corporation, Keybank National Association, The Royal Bank of Scotland Plc and Congress Financial Corporation. The agreements governing these various credit facilities subject us to various financial and other covenants with which we must comply on an ongoing or periodic basis. These include covenants pertaining to fixed charge coverage, capital expenditure, various leverage ratios, minimum EBITDA, total net worth and minimum cash requirement. If we violate any of these covenants, there may be a material adverse effect on us. Most notably, our outstanding debt under one or more of our credit

facilities could become immediately due and our ability to borrow additional funds in the future may be limited.

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

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

**Our acquisitions of the Unipath business, IVC Industries, Inc. and the Wampole Division of MedPointe Inc. may not be profitable or successfully integrated and may result in significant charges against earnings.**

On December 20, 2001, we acquired the Unipath business, including our Clearblue and Clearview product lines, from Unilever and certain affiliated entities. On March 19, 2002, we acquired IVC Industries, Inc. On September 20, 2002, we acquired the Wampole Division of MedPointe Inc. The value of the Unipath business, IVC or Wampole to us may not be greater than or equal to their purchase prices. Further, we cannot guarantee that we will realize any of the benefits or strategic objectives we are seeking to obtain by acquiring the Unipath business, IVC or Wampole. In connection with the accounting for the acquisitions of the Unipath business and Wampole, we have recorded a significant amount of intangible assets. Under Statement of Financial Accounting Standards No. 142, or SFAS No. 142, *Goodwill and Other Intangible Assets*, we must assess, at least annually and potentially more frequently, whether the value of goodwill and other intangible assets has been impaired. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings which could materially adversely affect our results of operations in future periods.

**We may not be able to complete our pending acquisition of Ostex International, Inc., in which case we will have incurred substantial expenses without realizing the expected benefits.**

Our pending acquisition of Ostex International, Inc., or Ostex, is subject to several closing conditions, most notably approval of the merger agreement governing the acquisition by Ostex's shareholders and the consent of our senior lender. As a result, there is no assurance that the acquisition will occur. If the acquisition does not occur, we expect to incur approximately $1.25 million to $1.75 million in acquisition related expenses. These expenses may have a material adverse impact on our results of operations and financial condition because we will not have realized the expected benefits of the acquisition of Ostex.

**If our pending acquisition of Ostex is completed, integration of operations may be difficult and may lead to adverse effects.**

The success of our pending acquisition of Ostex, if it is completed, will depend, in part, on our ability to realize the anticipated synergies, cost savings and growth opportunities from integrating Ostex's business with our business. Our success in realizing these benefits and the timing of this realization depend upon the successful integration of the operations of Ostex. The integration of two independent companies is a complex, costly and time-consuming process. The difficulties of combining the operations of the companies include among others:

- consolidating manufacturing, research and development operations;
- coordinating sales, distribution and marketing functions;
- preserving the important licensing, research and development, manufacturing and supply, distribution, marketing, customer and other relationships of Ostex;
- minimizing the diversion of management's attention from ongoing business concerns; and

- coordinating geographically separate organizations.

We may not accomplish this integration 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 the acquisition and adversely affect our other businesses.

**We expect to record a significant amount of goodwill and other intangible assets in connection with our pending acquisition of Ostex, which may result in significant future charges against earnings if the goodwill and other intangible assets become impaired.**

In connection with the accounting for the pending acquisition of Ostex, we expect to record a significant amount of goodwill and other intangible assets. Under SFAS No. 142, 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.

**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 significant dilution to our existing stockholders.**

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

- the inability to complete the acquisition or investment;
- disruption of our ongoing businesses and diversion of management attention;
- difficulties in integrating the acquired entities, products or technologies;
- difficulties in operating the acquired business profitably;
- the inability to achieve anticipated cost savings;
- potential loss of key employees, particularly those of the acquired business;
- difficulties in transitioning key customer, distributor and supplier relationships;
- risks associated with entering markets in which we have no or limited prior experience; and
- unanticipated costs.

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

- dilutive issuances of equity securities, which may be sold at a discount to market price;
- use of significant amounts of cash;
- the incurrence of debt;
- the assumption of liabilities;
- unfavorable financing terms;
- large one-time expenses; and

- the creation of certain intangible assets, including goodwill, the 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 we are unable to post a bond of $35 million, or some other amount determined by the Court, the preliminary injunction that we recently obtained against Pfizer, Inc.'s e.p.t. product will not take effect.**

On March 12, 2003, the United States District Court for the District of New Jersey entered an order granting our motion for a preliminary injunction against Pfizer, Inc., based on a finding that Pfizer's e.p.t® pregnancy tests, as manufactured by Mizuho USA, Inc., a subsidiary of Mizuho Medy, Ltd., likely infringe two of our patents. The Court's order effectively would preclude Pfizer from selling this version of its e.p.t. pregnancy test pending appeal, subject to our posting a $35 million bond with the Court. We have not posted the bond and may not be able to secure a sufficient bond at a reasonable cost. If we fail to post this bond, we may fail to realize the full benefits of the injunction imposed by the Court and we may lose the opportunity to increase our share of the market for pregnancy tests that we might have if Pfizer was forced to stop distributing is current version of its e.p.t. product.

**We could be liable for damages to Pfizer, Inc. if, despite preliminary injunctions preventing sale of Pfizer's e.p.t. pregnancy tests, the Court ultimately determines that e.p.t. does not infringe our patents.**

The United States District Court for the District of New Jersey has issued two preliminary injunctions that effectively preclude Pfizer, Inc. from selling existing versions of its e.p.t.® pregnancy tests based on findings that these tests likely infringe certain of our patents. Both preliminary injunctions were conditioned upon us posting bonds with Court and we have posted the bond on the first injunction. Despite the Court's findings that Pfizer's e.p.t. pregnancy tests likely infringe our patents, a final determination on whether these tests. infringe our patents will not be made until after a trial has occurred. The Court could rule against us at trial and find that these tests do not infringe our patents, in which case we could be held liable for damages to Pfizer for lost profits suffered during the period it was prohibited by the preliminary injunctions from selling such tests. In that case, we would lose any collateral provided by us to any surety for the bonds posted with the Court to the extent of any damages awarded to Pfizer and we would be liable to Pfizer and/or our surety provider(s) to the extent that damages awarded exceed collateral provided by us.

**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 U.S. Food and Drug Administration, 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 research and development center and serves as the administrative center for our European operations. We are currently using the Bedford facility pursuant to an agreement with Unilever entered into in connection with our acquisition of the Unipath business in 2001. Unilever currently leases this facility from a third party landlord. Pursuant to the terms of Unilever's lease, however, Unilever is not permitted to assign the lease or sublet the Bedford facility without obtaining the prior written consent of the landlord (which consent may not be unreasonably withheld). The landlord has indicated that it will not consent to an assignment of the lease to us. We, Unilever and the landlord are currently negotiating the terms of a sublease. The terms of our acquisition agreement obligate Unilever to use reasonable endeavors to obtain the landlord's consent to assignment or to a sublease of the facility and, if necessary, to pursue the assignment or sublease through the courts. There are no assurances that

Unilever will be successful in obtaining the landlord's consent to assignment of the lease to us or to a sublease to us. If Unilever is unable to successfully acquire such consent or otherwise enable us to realize the benefit of our lease of the Bedford facility, we may be forced to renegotiate a lease of the Bedford facility on substantially less favorable terms or seek alternative means of producing our products, conducting our research and housing our European administrative staff. In either case, we may experience manufacturing delays and disruptions to our ongoing research and development while we are resolving these issues and increased production costs in the future. Additionally, there are no assurances that we will be able to renegotiate a lease for the Bedford facility on terms that are acceptable to us or find an acceptable replacement for this facility. Any one or more of these events may have a material adverse effect on us.

**Manufacturing problems or delays could severely affect our business.**

We produce most of our consumer products in our manufacturing facilities located in New Jersey, Bedford, England and Galway, Ireland and some of our professional diagnostic tests in our manufacturing facilities located in Bedford, England 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 product 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. Any event impacting our manufacturing facilities, our manufacturing systems or equipment, or our contract manufacturers or suppliers could delay or suspend shipments of products, or could result in the delivery of inferior products. Our revenues from the affected products would decline 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.

**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 United States Food and Drug Administration, or the FDA, and, to a lesser extent, the United States Drug Enforcement Agency, or the DEA, and local health agencies. These regulatory agencies may conduct periodic inspections of our facilities to monitor our compliance with applicable regulatory standards. If a regulatory agency finds that we fail to comply with the appropriate regulatory standards, it may impose fines on us or if such a regulatory agency determines that our non-compliance is severe, it may close our facilities. Any adverse action by an applicable regulatory agency could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. 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.

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

Sales of our branded nutritional products have declined each year since 1998 until the year 2002 when they increased slightly as compared to 2001. We believe that those products have under-performed because they are, for the most part, aging brands with limited brand recognition that face increasing private label competition. The age of this product line means that we are subject to future distribution loss for under-performing brands, while our opportunities for new distribution on the existing product lines are limited. Despite the slight increase in sales seen during 2002, we do not expect significant sales growth of our existing branded nutritional products and we may experience further declines in sales of those 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 more than 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 more than 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. The current material legal proceedings are:

- a lawsuit by Abbott Laboratories against us and Princeton BioMeditech Corporation (referred to as PBM), which manufactured products for our consumer diagnostics business while we were part of IMT, claiming, among other things, that some of our products relating to pregnancy detection and ovulation prediction infringe patents to which Abbott asserts it is the exclusive licensee;
- a counterclaim by 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 have attempted to monopolize the market for home pregnancy tests; and
- an action brought by 68 consumers in London alleging defects in our Persona contraceptive device leading to unwanted pregnancies. We believe that any liability in this matter is fully covered by separate insurance provided by Unilever in connection with our acquisition of the Unipath business.

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

In connection with our split-off from IMT, we agreed to assume, to the extent permitted by law, and indemnify IMT for, 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, IVC and Wampole, we also assumed or acquired substantially all of the liabilities of those businesses. We are unable to assess the materiality or costs associated with these lawsuits at this time. We cannot assure you that these lawsuits or any future lawsuits relating to our businesses will not have a material adverse effect on us.

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

Our consumer products businesses rely to a great extent on close working relationships with our customers rather than long-term exclusive contractual arrangements. 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 effect 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.

**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 mass merchandisers will auction off the right to manufacture a particular product to the lowest, often anonymous bidder.

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

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

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

A significant number of our employees, including sales, support and research and development personnel, are located outside of the United States. Conducting business outside of the United States 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; and
- higher cost of sales resulting from import or export licensing requirements.

**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 42% of our net revenues were generated from outside the United States during 2002. Our Clearblue products, pregnancy tests in particular, have historically been much stronger brands outside the United States, with 68% of our net product sales of Clearblue products coming from outside the United States

during 2002. In addition, IMN generated almost 17.5% of its net product sales outside of the United States during 2002. In addition, 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 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, including the current armed conflict with the Palestinian authority or any armed conflict with Iraq.

**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:

- develope 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 consumer diagnostics business in certain foreign jurisdictions. In addition, many of our existing or potential competitors have or may have substantially greater research and development capabilities, clinical, manufacturing, regulatory and marketing experience and financial and managerial resources.

The market for the sale of vitamins and nutritional supplements is also highly competitive. This competition is based principally upon price, quality of products, customer service and marketing support. There are numerous companies in the vitamins and nutritional supplements industry selling products to retailers such as mass merchandisers, drug store chains, independent drug stores, supermarkets and health food stores. As most of these companies are privately held, we are unable to obtain the information necessary to assess precisely the size and success of these competitors. However,

we believe that a number of our competitors, particularly manufacturers of nationally advertised brand name products, are substantially larger than we are and have greater financial resources.

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

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

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

- the pending patent applications we have filed or to which we have exclusive rights may not result in issued patents or may take longer than we expect to result in issued patents;
- the claims of any patents which are issued may not provide meaningful protection;
- we may not be able to develop additional proprietary technologies that are patentable;
- the patents licensed or issued to us or our customers may not provide a competitive advantage;
- other companies may challenge patents licensed or issued to us or our customers;
- patents issued to other companies may harm our ability to do business; and
- other companies may design around technologies we have licensed or developed.

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

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

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

a successful claim of infringement 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 Inverness Medical Technology, Inc., or IMT, we agreed in the post-closing covenants agreement not to compete with IMT and Johnson & Johnson in the field of diabetes. In addition, Mr. Ron Zwanziger, our Chairman, President and Chief Executive Officer, and two of our senior scientists, Dr. David Scott and Dr. Jerry McAleer, have entered into consulting agreements with IMT that impose similar 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, and may never be made, we are unable to predict the amount, if any, that may be required for us to satisfy our indemnification obligations under these agreements. However, if claims are made for indemnification and we are liable for such claims, the amount could be substantial. In such an event, we may not have sufficient funds available to satisfy our potential indemnification obligations. In addition, we may be unable to obtain the funds on terms satisfactory to us, if at all. If we are unable to obtain the necessary funds, we will need to consider other alternatives, including sales of assets, to raise necessary funds.

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

Although we have dismissed Arthur Andersen LLP as our independent public accountants and have engaged Ernst & Young LLP, the following financial statements incorporated by reference into this Annual Report on Form 10-K were audited by Arthur Andersen:

- the consolidated financial statements of Inverness as of December 31, 2001 and 2000, and for each of the three years in the period ended December 31, 2001; and
- the financial statements of the Unipath Division of Unilever plc as of November 30, 2001 and December 31, 2000, and for the eleven months ended November 30, 2001 and each of the two years in the period ended December 31, 2000.

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. In addition, Arthur Andersen has not consented to the inclusion of its report in this document, and the requirement to file its consent has been dispensed with in reliance on Rule 2-02(e) of Regulation S-X. Because Arthur Andersen has not consented to the inclusion of its report in this document, you will not be able to recover against Arthur Andersen under Section 11 of the Securities Act 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;

- the availability and extent of reimbursement for our products;
- increased research and development expenses;
- the timing of any future acquisitions;
- general economic conditions; or
- general stock market conditions or other economic or external factors.

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

Our common stock has only been listed on the American Stock Exchange since November 23, 2001 and we have a limited market capitalization. As a result, we are currently followed by only a few market analysts and a portion of the investment community. Limited trading of our common stock may therefore make it more difficult for you to sell your shares.

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

- our quarterly and annual operating results, including our failure to meet the performance estimates of securities analysts;
- changes in financial estimates of our revenues and operating results or buy/sell recommendations by securities analysts;
- the timing of announcements by us or our competitors of significant products, contracts or acquisitions or publicity regarding actual or potential results or performance thereof;
- changes in general conditions in the economy, the financial markets or the health care industry;
- government regulation in the health care industry;
- changes in other areas such as tax laws;
- sales of substantial amounts of common stock or the perception that such sales could occur;
- changes in investor perception of our industry, our businesses or our prospects;
- the loss of key employees, officers or directors; or
- other developments affecting us or our competitors.

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

As of December 31, 2002, there were 323,060 shares of our Series A Preferred Stock outstanding. Pursuant to the terms of the certificate of designation creating our Series A Preferred Stock, upon a liquidation or a deemed liquidation of our company, the holders of the shares of our Series A Preferred Stock are entitled to receive a liquidation payment prior to the payment of any amount with respect to the shares of our common stock. The amount of this preferential liquidation payment is $30 per share of our Series A Preferred Stock (or $40.50 per share in certain circumstances), plus the amount of any dividends that have accrued on those shares, subject to adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization affecting our Series A Preferred Stock. Dividends accrue on the shares of our Series A Preferred Stock at the rate of up to

$2.10 per share per annum based on the percentage of trading days on which the closing market price of our common stock is less than $15.00. As a result of these terms, the holders of our common stock may be disproportionately affected by any reduction in the value of our assets or fluctuations in the market price of our common stock.

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

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

- our certificate of incorporation provides for three classes of directors with the term of office of one class expiring each year, commonly referred to as a staggered board. By preventing stockholders from voting on the election of more than one class of directors at any annual meeting of stockholders, this provision may have the effect of keeping the current members of our board of directors in control for a longer period of time than stockholders may desire; and
- our certificate of incorporation authorizes our board of directors to issue shares of preferred stock without stockholder approval and to establish the preferences and rights of any preferred stock issued, which would allow the board to issue one or more classes or series of preferred stock that could discourage or delay a tender offer or change in control.

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

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

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

**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 Inverness Medical Technology, Inc., or 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 Securities and Exchange Commission 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.

## SPECIAL STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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 Annual Report on Form 10-K. These differences may be the result of various factors, including those factors described in the "Certain Factors Affecting Future Results" section in this Annual Report and other risk factors identified from time to time in our periodic filings with the Securities and Exchange Commission. Some important additional factors that could cause our actual results to differ materially from those projected in any such forward-looking statements are as follows:

- economic factors, including inflation and fluctuations in interest rates and foreign currency exchange rates, and the potential effect of such fluctuations on revenues, expenses and resulting margins;
- competitive factors, including technological advances achieved and patents attained by competitors and generic competition;
- domestic and foreign healthcare changes resulting in pricing pressures, including the continued consolidation among healthcare providers, trends toward managed care and healthcare cost containment and government laws and regulations relating to sales and promotion, reimbursement and pricing generally;
- government laws and regulations affecting domestic and foreign operations, including those relating to trade, monetary and fiscal policies, taxes, price controls, regulatory approval of new products and licensing;
- manufacturing interruptions, delays or capacity constraints or lack of availability of alternative sources for components for our products, 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 pending acquisition of Ostex, and organizational restructurings consistent with evolving business strategies;
- our ability to satisfy the financial covenants and other conditions contained in our credit facilities;
- our ability to obtain required financing on terms that are acceptable to us; and
- the issuance of new or revised accounting standards by the American Institute of Certified Public Accountants, the Financial Accounting Standards Board or the Securities and Exchange Commission.

The foregoing list sets forth many, but not all, of the factors that could impact upon our ability to achieve results described in any forward-looking statements. Readers should not place undue reliance on our forward-looking statements. Before you invest in our common stock, you should be aware that the occurrence of the events described above and elsewhere in this Annual Report on Form 10-K 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, 2002, our short-term investments approximated market value.

At December 31, 2002, we had a U.S. term loan of $20.0 million and a European term loan of $10.0 million outstanding and $23.0 million outstanding borrowings on a European revolving line of credit under our senior credit agreement. Principal repayments under the U.S. term loan are to be made in eleven equal quarterly installments of $1.25 million starting on April 30, 2003 through October 31, 2005 with a final installment of $6.25 million due in November 2005. Principal repayments under the European term loan are to be made in fourteen equal quarterly installments of $25,000 starting on January 31, 2003 through April 30, 2006 with a final installment of $9.65 million due in May 2006. Any borrowings under the revolving line of credit will mature on November 14, 2005. Borrowings under the term loans and the revolving line of credit bear interest at either (i) the London

Interbank Offered Rate ("LIBOR"), as defined in the credit agreement, plus applicable margins or, at our option, (ii) floating at the Index Rate, as defined in the credit agreement, plus applicable margins. Applicable margins, depending on the type of loan, can range from 1.25% to 3.75% and are subject to quarterly adjustments based on our total leverage ratio, as defined in the credit agreement.

We have an interest rate swap agreement with a bank in place, which will 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 $39.0 million of our 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, 2002, the LIBOR and Index rates applicable under the senior credit agreement were 1.38% and 4.25%, respectively. Assuming no changes in our leverage ratio which would have affected the margin of the interest rates, the effect of interest rate fluctuations on the loans under the senior credit agreement over the next twelve months is quantified and summarized as follows:

| | Interest Expense Increase |
|---|---|
| If compared to the rate at December 31, 2002, | |
| LIBOR increases by 1% point | $ 513,000 |
| LIBOR increases by 2% point | 1,017,000 |
| Index Rate increases by 1% point | $ 513,000 |
| Index Rate increases by 2% point | 1,027,000 |

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 16, 2003. As of December 31, 2002, total borrowings outstanding under the credit agreement with the bank were $11.7 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, 2002, the interest rate on $4.3 million of the outstanding borrowings was at the Adjusted Eurodollar Rate of 0.9% plus the spread of 3.75% and the interest rate on the remaining $7.5 million of the outstanding borrowings was at the prime rate of 4.25% 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 is quantified and summarized as follows:

| | Interest Expense Increase |
|---|---|
| If compared to the rate at December 31, 2002, | |
| Interest rate increases by 1% point | $ 90,000 |
| Interest rate increases by 2% point | 183,000 |

*Foreign Currency Risk*

We face exposure to movements in foreign currency exchange rates. During 2002, the net impact of foreign currency changes was a gain of $1.0 million, which included a one-time realized foreign exchange transaction gain of $2.6 million upon the settlement of an inter-company loan between two of our subsidiaries with different functional currencies. Excluding such one-time foreign exchange gain, we incurred foreign exchange losses of $1.6 million in 2002. The loss in 2002 resulted from the weakened U.S. Dollar against the Japanese Yen, in which a portion of our bank debt, which was refinanced in November 2002, was denominated, and the weakened U.S. Dollar against the Euro, the functional currency of certain of our subsidiaries that have receivables and payables denominated in U.S. Dollars.

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. In addition, because significant amounts of the revenue and expenses of our Unipath business are denominated in foreign currencies, our Unipath business has historically utilized and will continue to utilize short-term foreign exchange forward contracts to minimize exposure to the risk that the eventual net cash inflows and outflows resulting from the sale of products to foreign customers and purchases from foreign suppliers will be adversely affected by changes in exchange rates. Our goal is to utilize short-term foreign exchange forward contracts for recognized receivables and payables and firmly committed cash inflows and outflows, which allow us to reduce our overall exposure to exchange rate movements, since the gains and losses on these contracts are expected to substantially offset losses and gains on the assets, liabilities and transactions to which these contracts relate. Cash inflows and outflows denominated in the same foreign currency are netted on a legal entity basis and the corresponding net cash flow exposure is appropriately hedged. As of December 31, 2002, we did not have outstanding foreign exchange forward contracts.

## 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 ACCOUNTANTS

Arthur Andersen LLP served as our independent public accountant during our initial fiscal year ended December 31, 2001. On June 28, 2002, upon the recommendation of the Audit Committee, the Board of Directors of the Company dismissed Arthur Andersen and engaged Ernst & Young LLP. Our decision to change accountants was the result of Arthur Andersen's legal difficulties, the resultant personnel departures and Arthur Andersen's decision to discontinue its auditing practice by August 31, 2002.

Arthur Andersen's report on the Company's financial statements for fiscal year 2001 did not contain an adverse opinion or a disclaimer of opinion, and was not qualified or modified as to uncertainty, audit scope or accounting principles.

During our initial fiscal year and the subsequent interim periods preceding the decision to change independent accountants, we had no disagreements with Arthur Andersen on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which, if not resolved to the satisfaction of Arthur Andersen, would have caused Arthur Andersen to make reference to the subject matter of the disagreement in connection with its report on the Company's financial statements. Moreover, there were no reportable events, as described in Item 304(a)(1)(v) of Regulation S-K.

During our initial fiscal year and the subsequent interim periods preceding the decision to engage Ernst & Young as our independent auditors, we did not consult Ernst & Young, and no one consulted Ernst & Young on our behalf, regarding the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, or any reportable event (as described in Item 304(a)(1)(v)) of Regulation S-K).

## 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 2003 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. CONTROLS AND PROCEDURES

(a) Evaluation of disclosure controls and procedures

As required by new Rule 13a-15 under the Securities Exchange Act of 1934, within the 90 days prior to the date of this report, we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Vice President of Finance (our principal financial officer), of the effectiveness of the design and operation of our company's disclosure controls and procedures. In designing and evaluating our disclosure controls and procedures, we and our management recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating and implementing possible controls and procedures. Based upon the required evaluation, our Chief Executive Officer and Vice President of Finance believe that, as of the date of completion of the evaluation, our company's disclosure controls and procedures were effective to ensure that information we are required to disclose in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Securities and Exchange Commission's rules and forms.

In connection with the adoption and implementation of the rules described above and from time to time thereafter, we have conducted and will continue to conduct further reviews and, from time to time put in place additional documentation of, our disclosure controls and procedures, including our internal controls and procedures for financial reporting. We may from time to time make changes aimed at enhancing their effectiveness, as well as changes aimed at ensuring that our systems evolve with, and meet the needs of, our business. These changes may include changes necessary or desirable to address recommendations of our management and/or our independent auditors, including any recommendations of our independent auditors arising out of their recently completed audit, and any future audits, of our financial statements. These changes may include changes to our own systems, as well as to the systems of businesses that we have acquired or that we may acquire in the future and will, if made, be intended to enhance the effectiveness of our controls and procedures.

(b) Changes in internal controls

None.

## 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 Amended and Restated Agreement and Plan of Merger, made and entered into as of December 21, 2001 and amended and restated as of January 22, 2002, by and among the Company, Nutritionals Acquisition Corporation and IVC Industries, Inc. ("IVC") (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated March 29, 2002)

2.3 Asset Purchase Agreement by and among MedPointe Inc., The CPI Development Corporation, MedPointe Healthcare Inc., Inverness Medical Innovations, Inc. and W.L. Acquisition Corp. dated as of August 7, 2002 (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K dated September 20, 2002)

2.4 Agreement and Plan of Merger dated as of September 6, 2002, 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 on Form 8-K dated September 9, 2002)

2.5 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)

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) |
| 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)) |
| 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 Agreement, dated as of December 20, 2001, by and between the Company and RBS Mezzanine Limited (incorporated by reference to Exhibit 10.26 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

10.22 Warrant to Purchase Common Stock of the Company, dated December 20, 2001, issued to RBS Mezzanine Limited in connection with the Mezzanine Loan Agreement (incorporated by reference to Exhibit 10.27 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2001)

10.23 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)

10.24 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)

10.25 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)

10.26 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)

10.27 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)

10.28 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)

10.29 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)

10.30 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))

10.31 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)

10.32 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)

10.33 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)

10.34 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)

10.35 Inverness Medical Innovation, Inc. 2001 Employee Stock Purchase Plan German Sub-Plan (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, as amended, for the period ended March 30, 2002)

10.36 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))

10.37 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)

10.38 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)

10.39 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)

10.40 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)

10.41 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)

10.42 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)

10.43 Credit Agreement dated as of November 14, 2002 among Wampole Laboratories, Inc. and Inverness Medical (UK) Holdings Limited, as Borrowers, the other credit parties signatory hereto, as Credit Parties, the lenders signatory hereto from time to time, as Lenders, General Electric Capital Corporation, as Agent and Lender, and KeyBank National Association, as Documentation Agent and Lender, with GECC Capital Markets Group, Inc., as Lead Arranger (incorporated by reference to Exhibit 99.1 to the Company's Current Report on Form 8-K dated November 14, 2002)

16.1 Letter from Arthur Andersen LLP to the Securities and Exchange Commission dated June 28, 2002 (incorporated by reference to Exhibit 16.1 to the Company's Current Report on Form 8-K dated June 28, 2002)

*21.1 List of Subsidiaries of the Company as of March 26, 2003

*23.1 Consent of Ernst & Young LLP

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* Filed herewith.

(b) *Reports on Form 8-K*

On October 4, 2002 we filed a Current Report on Form 8-K dated September 20, 2002 (Item 2) in connection with our entry into a definitive agreement to acquire the Wampole Laboratories unit of MedPointe Inc.

On October 8, 2002 we filed a Current Report on Form 8-K/A dated September 20, 2002 (Item 2) in connection with our entry into a definitive agreement to acquire the Wampole Laboratories unit of MedPointe Inc.

On October 24, 2002 we filed a Current Report on Form 8-K dated October 24, 2002 (Item 9) in connection with our press release and conference call relating to our financial results for the third quarter of 2002.

On November 6, 2002 we filed a Current Report on Form 8-K/A (Amendment No. 2) dated September 20, 2002 (Item 7) in order to file the financial statements and pro forma financial information required by Item 7 of Form 8-K, in connection with our acquisition of the Wampole Laboratories unit of MedPointe Inc.

On November 14, 2002 we filed a Current Report on Form 8-K dated November 13, 2002 (Item 9) in order to furnish the certification of the Chief Executive Officer and the Vice President of Finance of the Company that accompanied our Quarterly Report on Form 10-Q for the period ending September 30, 2002.

On November 19, 2002 we filed a Current Report on Form 8-K dated November 14, 2002 (Item 5) in connection with our entry into a credit agreement with a group of banks.

On December 9, 2002 we filed a Current Report on Form 8-K dated December 9, 2002 (Item 9) in connection with a presentation intended to be made to potential investors.

## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INVERNESS MEDICAL INNOVATIONS, INC.

Date: March 31, 2003

By: /s/ RON ZWANZIGER
Ron Zwanziger
*Chairman, President and Chief Executive Officer*

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

| Signature | Title | Date |
|---|---|---|
| /s/ RON ZWANZIGER<br>Ron Zwanziger | President, Chief Executive Officer and Director (Principal Executive Officer) | March 31, 2003 |
| /s/ DUANE L. JAMES<br>Duane L. James | Vice President of Finance and Treasurer (Principal Financial Officer and Principal Accounting Officer) | March 31, 2003 |
| /s/ ERNEST A. CARABILLO, JR.<br>Ernest A. Carabillo, Jr. | Director | March 31, 2003 |
| /s/ CAROL R. GOLDBERG<br>Carol R. Goldberg | Director | March 31, 2003 |
| /s/ ROBERT P. KHEDERIAN<br>Robert P. Khederian | Director | March 31, 2003 |
| /s/ JOHN F. LEVY<br>John F. Levy | Director | March 31, 2003 |
| /s/ DAVID SCOTT<br>David Scott | Director | March 31, 2003 |

| Signature | Title | Date |
|---|---|---|
| /s/ PETER TOWNSEND<br>Peter Townsend | Director | March 31, 2003 |
| /s/ ALFRED M. ZEIEN<br>Alfred M. Zeien | Director | March 31, 2003 |
| /s/ JERRY MCALEER<br>Jerry McAleer | Director | March 31, 2003 |
| /s/ JOHN A. QUELCH<br>John A. Quelch | Director | March 31, 2003 |

## CERTIFICATIONS

I, Ron Zwanziger, certify that:

1. I have reviewed this Annual Report on Form 10-K of Inverness Medical Innovations, Inc.;

2. Based on my knowledge, this Annual Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Annual Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Annual Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Annual Report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Annual Report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this Annual Report (the "Evaluation Date"); and

c) Presented in this Annual Report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors:

a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this Annual Report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 31, 2003

/s/ RON ZWANZIGER

Ron Zwanziger
*Chairman, President and Chief Executive Officer*

I, Duane L. James, certify that:

1. I have reviewed this Annual Report on Form 10-K of Inverness Medical Innovations, Inc.;

2. Based on my knowledge, this Annual Report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this Annual Report;

3. Based on my knowledge, the financial statements, and other financial information included in this Annual Report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this Annual Report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:

a) Designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this Annual Report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this Annual Report (the "Evaluation Date"); and

c) Presented in this Annual Report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors:

a) All significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and

6. The registrant's other certifying officer and I have indicated in this Annual Report whether or not there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 31, 2003

/s/ DUANE L. JAMES

Duane L. James
*Vice President, Finance and Treasurer*

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INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

Table of Contents

## REPORT OF INDEPENDENT AUDITORS

The Board of Directors and Stockholders of
Inverness Medical Innovations, Inc. and Subsidiaries:

We have audited the accompanying consolidated balance sheet of Inverness Medical Innovations, Inc. and Subsidiaries (the "Company") as of December 31, 2002, and the related consolidated statements of operations, stockholders' equity, and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit. The consolidated financial statements of the Company as of December 31, 2001, and for each of the two years in the period ended December 31, 2001 were audited by other auditors who have ceased operations and whose report dated March 28, 2002, expressed an unqualified opinion on those statements before the reclassifications and adjustments described in Notes 2(o) and 5.

We conducted our audit in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the 2002 consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Inverness Medical Innovations, Inc. and Subsidiaries at December 31, 2002, and the consolidated results of their operations and their cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States.

As discussed above, the financial statements of the Company as of December 31, 2001 and 2000 and for each of the years then ended were audited by other auditors who have ceased operations. As described in Notes 2(o) and 5, in 2002 the Company adopted the accounting required pursuant to Emerging Issues Task Force ("EITF") Issue No. 01-09, *Accounting for Consideration Given by a Vendor to a Customer or a Reseller of the Vendor's Products,* and Statement of Financial Accounting Standards ("SFAS") No. 142, *Goodwill and Other Intangible Assets*. The 2001 and 2000 consolidated financial statements have been adjusted to reclassify certain amounts between net product sales and sales and marketing expenses in the statements of operations, as required by EITF Issue No. 01-09, and the notes to the financial statements disclose the effect of adjusting the statements of operations to exclude goodwill amortization for 2001 and 2000, as required by SFAS No. 142.

We audited the adjustments disclosed in Note 2(o) that were applied to reclassify certain amounts between net product sales and sales and marketing expenses in the statements of operations. Our procedures included (i) agreeing the adjusted amounts of net product sales and sales and marketing expenses to the Company's underlying accounting records obtained from management and (ii) testing the mathematical accuracy of the adjusted amounts of net product sales and sales and marketing expenses. Our audit procedures with respect to goodwill disclosures in Note 5 relating to 2001 and 2000 included (i) agreeing the previously reported net income (loss) and the adjustments to reported net income (loss) representing amortization expense recognized in 2001 and 2000 related to goodwill to the previously issued financial statements and underlying accounting records obtained from management and (ii) testing the mathematical accuracy of the reconciliation of adjusted net income (loss) to

reported net income (loss) and the related earnings (loss) per share amounts. In our opinion, such adjustments and disclosures are appropriate and have been properly applied. However, we were not engaged to audit, review, or apply any procedures to the 2001 and 2000 consolidated financial statements of the Company other than with respect to such adjustments and, accordingly, we do not express an opinion or any other form of assurance on the consolidated financial statements as of December 31, 2001 and 2000 and for the years then ended taken as a whole.

Ernst & Young LLP

Boston, Massachusetts
February 20, 2003

*Provided below, pursuant to Rule 2-02(e) of Regulation S-X, is a copy of the accountants report issued by Arthur Andersen LLP, our former independent public accountants, in connection with the filing of our Annual Report of Form 10-K for the year ended December 31, 2001.* ***This audit report has not been reissued by Arthur Andersen in connection with the filing of this Annual Report on Form 10-K for the year ended December 31, 2002.*** *We are unable to obtain a reissued accountants report from Arthur Andersen, and we will be unable to obtain future accountants reports from Arthur Andersen, because Arthur Andersen has discontinued its auditing practice. This means that we will also be unable to obtain consents to incorporate any financial statements audited by Arthur Andersen into registration statements that we may file in the future. Accordingly, investors will not be able to sue Arthur Andersen pursuant to section 11(a)(4) of the Securities Act with respect to any such registration statements and, therefore, ultimate recovery on a successful claim may be limited. The ability of investors to recover from Arthur Andersen may also be limited as a result of Arthur Andersen's financial condition or other matters resulting from the various civil and criminal lawsuits against that firm.*

## REPORT OF INDEPENDENT PUBLIC ACCOUNTANTS

To Inverness Medical Innovations, Inc.:

We have audited the accompanying consolidated balance sheets of Inverness Medical Innovations, Inc. (a Delaware corporation) and subsidiaries as of December 31, 2001 and 2000, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the three years in the period ended December 31, 2001. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Inverness Medical Innovations, Inc. and subsidiaries as of December 31, 2001 and 2000, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2001, in conformity with accounting principles generally accepted in the United States.

**ARTHUR ANDERSEN LLP**

Boston, Massachusetts
March 28, 2002

## INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
## CONSOLIDATED STATEMENTS OF OPERATIONS

| | 2002 | 2001 | 2000 |
|---|---|---|---|
| Net product sales | $201,492,065 | $ 47,267,674 | $49,727,547 |
| License revenue | 6,405,331 | — | — |
| Net Revenue | 207,897,396 | 47,267,674 | 49,727,547 |
| Cost of sales | 112,507,916 | 26,148,571 | 26,234,870 |
| Gross profit | 95,389,480 | 21,119,103 | 23,492,677 |
| Operating expenses: | | | |
| Purchased in-process research and development (Note 4(c)) | — | 6,980,221 | — |
| Research and development | 14,470,767 | 1,809,508 | 1,359,500 |
| Sales and marketing | 42,486,721 | 8,531,211 | 8,101,319 |
| General and administrative | 28,066,837 | 11,702,376 | 7,047,653 |
| Charge related to asset impairment (Note 5) | 12,681,581 | — | — |
| Stock-based compensation(1) (Note 12(c)) | 10,624,893 | 10,440,588 | — |
| Total operating expenses | 108,330,799 | 39,463,904 | 16,508,472 |
| Operating (loss) income | (12,941,319) | (18,344,801) | 6,984,205 |
| Interest expense, including amortization of discounts (Note 6) | (9,376,371) | (1,967,319) | (2,035,472) |
| Other income (expense), net | 884,197 | (2,015,723) | (387,884) |
| (Loss) income from continuing operations before income taxes | (21,433,493) | (22,327,843) | 4,560,849 |
| Provision for income taxes | 2,683,292 | 2,134,359 | 1,781,244 |
| (Loss) income from continuing operations | (24,116,785) | (24,462,202) | 2,779,605 |
| Income (loss) from discontinued operations, net of taxes (Note 15(d)) | — | 57,895 | (597,784) |
| (Loss) income before extraordinary items and cumulative effect of a change in accounting principle | (24,116,785) | (24,404,307) | 2,181,821 |
| Extraordinary gain (loss) on early extinguishment of debt (Note 6) | 5,129,989 | (326,580) | — |
| Cumulative effect of a change in accounting principle (Note 5) | (12,148,205) | — | — |
| Net (loss) income | $(31,135,001) | $(24,730,887) | $ 2,181,821 |
| (Loss) income available to common stockholders (Note 11): | | | |
| (Loss) income from continuing operations | $(36,065,242) | $(24,462,202) | $ 2,779,605 |
| Net (loss) income | $(43,083,458) | $(24,730,887) | $ 2,181,821 |
| (Loss) income per common share—basic and diluted (Notes 2(k) and 11): | | | |
| (Loss) income from continuing operations | $ (3.63) | $ (3.84) | $ 0.59 |
| Net (loss) income | $ (4.33) | $ (3.88) | $ 0.46 |
| Weighted average shares | 9,939,664 | 6,367,657 | 4,726,390 |
| (1) Stock-based compensation expense by statement of operations classifications is as follows: | | | |
| Research and development | $ 36,728 | $ 9,345,528 | $ — |
| Sales and marketing | 26,328 | — | — |
| General and administrative | 10,561,837 | 1,095,060 | — |
| Total stock-based compensation | $ 10,624,893 | $ 10,440,588 | $ — |

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

## INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
## CONSOLIDATED BALANCE SHEETS

| | December 31, 2002 | December 31, 2001 |
|---|---|---|
| **ASSETS** | | |
| **Current assets:** | | |
| Cash and cash equivalents | $ 30,668,330 | $ 52,023,531 |
| Accounts receivable, net of allowances of $7,047,274 and $2,595,137 at December 31, 2002 and 2001, respectively | 37,283,052 | 21,576,203 |
| Inventory | 37,154,398 | 14,781,990 |
| Deferred tax assets | 2,136,991 | — |
| Prepaid expenses and other current assets | 6,684,976 | 4,973,659 |
| **Total current assets** | 113,927,747 | 93,355,383 |
| Property, plant and equipment, net | 45,800,089 | 20,526,228 |
| Goodwill, net | 108,914,675 | 85,375,217 |
| Trademarks and trade name with indefinite lives | 31,718,609 | 25,698,609 |
| Core technology and patents, net | 25,804,797 | 23,865,678 |
| Other intangible assets, net | 22,373,923 | 25,826,109 |
| Deferred financing costs and other assets, net | 4,908,361 | 2,407,134 |
| Deferred tax assets | 4,297,473 | 1,466,786 |
| **Total assets** | $357,745,674 | $278,521,144 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| **Current liabilities:** | | |
| Current portion of long-term debt | $ 17,200,390 | $ 20,819,383 |
| Current portion of capital lease obligations | 641,901 | — |
| Accounts payable | 27,494,930 | 10,264,023 |
| Accrued expenses and other current liabilities | 40,381,464 | 42,716,768 |
| **Total current liabilities** | 85,718,685 | 73,800,174 |
| **Long-term liabilities:** | | |
| Long-term debt | 84,533,111 | 57,304,834 |
| Capital lease obligations | 2,238,171 | — |
| Deferred tax liabilities | 9,365,014 | 2,044,019 |
| Other liabilities | 3,935,269 | 3,863,550 |
| **Total long-term liabilities** | 100,071,565 | 63,212,403 |
| **Commitments and contingencies (Note 10)** | | |
| **Series A redeemable convertible preferred stock, $0.001 par value:** | | |
| Authorized—2,666,667 shares | | |
| Issued and outstanding—323,060 and 1,995,000 shares at December 31, 2002 and 2001, respectively | 9,051,292 | 51,894,435 |
| **Stockholders' equity:** | | |
| Preferred stock, $0.001 par value | | |
| Authorized—2,333,333 shares, none issued | — | — |
| Common stock, $0.001 par value: | | |
| Authorized—50,000,000 shares | | |
| Issued and outstanding—14,907,191 and 8,681,744 shares at December 31, 2002 and 2001, respectively | 14,907 | 8,682 |
| Additional paid-in capital | 251,457,598 | 147,410,812 |
| Notes receivable from stockholders | (14,691,097) | (14,691,097) |
| Deferred compensation | (48,172) | (10,144,937) |
| Accumulated deficit | (77,720,030) | (34,636,572) |
| Accumulated other comprehensive income | 3,890,926 | 1,667,244 |
| **Total stockholders' equity** | 162,904,132 | 89,614,132 |
| **Total liabilities and stockholders' equity** | $357,745,674 | $278,521,144 |

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

## INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

| | Common Stock | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Number of Shares | $0.001 Par Value | Additional Paid-in Capital | Notes Receivable from Stockholders | Deferred Compensation | Accumulated Deficit | Accumulated Other Comprehensive (Loss) Income | Total Stockholders' Equity | Comprehensive (Loss) Income |
| BALANCE, DECEMBER 31, 1999 | 3,641,856 | $ 3,642 | $ 52,583,675 | $ — | $ — | $(18,250,539) | $ 616,238 | $ 34,953,016 | |
| Common stock issued by IMT effected by exchange ratio and related stock split (Note 2(k)) | 2,185,859 | 2,186 | (2,186) | — | — | — | — | — | $ — |
| Capital contribution from IMT related to income taxes for Inverness Medical, Inc | — | — | 2,558,517 | — | — | — | — | 2,558,517 | — |
| Net cash contributed by IMT | — | — | 1,969,054 | — | — | — | — | 1,969,054 | — |
| Changes in cumulative translation adjustment | — | — | — | — | — | — | 149,642 | 149,642 | 149,642 |
| Net (loss) income | — | — | (2,269,835) | — | — | 4,451,656 | — | 2,181,821 | 2,181,821 |
| Total comprehensive income | | | | | | | | | 2,331,463 |
| BALANCE, DECEMBER 31, 2000 | 5,827,715 | 5,828 | 54,839,225 | — | — | (13,798,883) | 765,880 | 41,812,050 | |
| Common stock issued by IMT effected by exchange ratio and related stock split (Note 2(k)) | 756,859 | 757 | (757) | — | — | — | — | — | — |
| Capital contribution from IMT related to income taxes for Inverness Medical, Inc | — | — | 986,694 | — | — | — | — | 986,694 | — |
| Capital contribution from IMT in connection with split-off (Note 1) | — | — | 46,712,368 | — | — | — | — | 46,712,368 | — |
| Exercise of common stock options and warrants | 279,598 | 279 | 567,571 | — | — | — | — | 567,850 | — |
| Issuance of stock for notes receivable | 1,817,572 | 1,818 | 14,689,929 | (14,691,097) | — | — | — | 650 | — |
| Deferred compensation (Notes 1 and 12(c)) | — | — | 20,585,525 | — | (20,585,525) | — | — | — | — |
| Amortization of deferred compensation expense (Notes 1 and (12(c)) | — | — | — | — | 10,440,588 | — | — | 10,440,588 | — |
| Beneficial conversion feature on issuance of series A redeemable convertible preferred stock, net of issuance costs of $52,111 (Note 12(b)) | — | — | 7,927,889 | — | — | — | — | 7,927,889 | — |
| Amortization of beneficial conversion feature related to series A redeemable convertible preferred stock (Note 12(b)) | — | — | — | — | — | (24,429) | — | (24,429) | — |
| Original issue discount and beneficial conversion feature on issuance of convertible debt (Notes 6(f) and (g)) | — | — | 5,019,995 | — | — | — | — | 5,019,995 | — |
| Changes in cumulative translation adjustment | — | — | — | — | — | — | 901,364 | 901,364 | 901,364 |
| Net loss | — | — | (3,917,627) | — | — | (20,813,260) | — | (24,730,887) | (24,730,887) |
| Total comprehensive loss | | | | | | | | | (23,829,523) |
| BALANCE, DECEMBER 31, 2001 | 8,681,744 | 8,682 | 147,410,812 | (14,691,097) | (10,144,937) | (34,636,572) | 1,667,244 | 89,614,132 | |

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

## INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (Continued)

| | Common Stock | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Number of Shares | $0.001 Par Value | Additional Paid-in Capital | Notes Receivable from Stockholders | Deferred Compensation | Accumulated Deficit | Accumulated Other Comprehensive (Loss) Income | Total Stockholders' Equity | Comprehensive (Loss) Income |
| BALANCE, DECEMBER 31, 2001 | 8,681,744 | $ 8,682 | $147,410,812 | $(14,691,097) | $(10,144,937) | $(34,636,572) | $1,667,244 | $ 89,614,132 | |
| Issuance of common stock, net of issuance costs of $2,521,443 | 1,600,000 | 1,600 | 34,276,957 | — | — | — | — | 34,278,557 | $ — |
| Exercise of common stock options and warrants | 217,741 | 217 | 1,043,315 | — | — | — | — | 1,043,532 | — |
| Conversion of series A redeemable convertible preferred stock to common stock | 4,407,706 | 4,408 | 67,877,560 | — | — | (8,811,624) | — | 59,070,344 | — |
| Excess of redemption value related to issuance of series A redeemable convertible preferred stock, net of issuance costs of $182,800 (Note 12(b)) | — | — | 4,609,809 | — | — | — | — | 4,609,809 | — |
| Beneficial conversion feature on issuance of series A redeemable convertible preferred stock (Note 12(b)) | — | — | 2,867,011 | — | — | — | — | 2,867,011 | — |
| Dividends related to series A redeemable convertible preferred stock (Note 12(b)) | — | — | — | — | — | (325,725) | — | (325,725) | — |
| Interest and amortization of beneficial conversion feature related to series A redeemable convertible preferred stock (Note 12(b)) | — | — | — | — | — | (2,811,108) | — | (2,811,108) | — |
| Beneficial conversion feature related to early extinguishment of convertible debt (Notes 6(g)) | — | — | (9,600,000) | — | — | — | — | (9,600,000) | — |
| Warrants issued with subordinated debt (Note 6(b)) | — | — | 1,502,008 | — | — | — | — | 1,502,008 | — |
| Fair value of assumed and issued fully-vested stock options related to acquisition of IVC Industries, Inc. (Note 4(b)) | — | — | 1,298,674 | — | — | — | — | 1,298,674 | — |
| Stock-based compensation related to grants of common stock options and warrants to non-employees | — | — | 477,299 | — | — | — | — | 477,299 | — |
| Deferred compensation related to grants of common stock options to non-employees | — | — | 50,829 | — | (50,829) | — | — | — | — |
| Amortization of deferred compensation (Note 12(c)) | — | — | — | — | 10,147,594 | — | — | 10,147,594 | — |
| Other | — | — | (356,676) | — | — | — | — | (356,676) | — |
| Changes in cumulative translation adjustment | — | — | — | — | — | — | 2,223,682 | 2,223,682 | 2,223,682 |
| Net loss | — | — | — | — | — | (31,135,001) | — | (31,135,001) | (31,135,001) |
| Total comprehensive loss | | | | | | | | | $(28,911,319) |
| BALANCE, DECEMBER 31, 2002 | 14,907,191 | $14,907 | $251,457,598 | $(14,691,097) | $ (48,172) | $(77,720,030) | $3,890,926 | $162,904,132 | |

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

## INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

## CONSOLIDATED STATEMENTS OF CASH FLOWS

| | 2002 | 2001 | 2000 |
|---|---|---|---|
| **Cash Flows from Operating Activities:** | | | |
| Net (loss) income | $(31,135,001) | $ (24,730,887) | $ 2,181,821 |
| (Income) loss from discontinued operations | — | (57,895) | 597,784 |
| Net (loss) income, excluding discontinued operations | (31,135,001) | (24,788,782) | 2,779,605 |
| Adjustments to reconcile net (loss) income to net cash provided by operating activities: | | | |
| Interest expense related to amortization of noncash original issue discount, noncash beneficial conversion feature and deferred financing costs | 3,273,927 | 542,687 | 130,776 |
| Noncash charge related to interest rate swap agreement | 1,223,146 | — | — |
| Noncash stock-based compensation expense | 10,624,893 | 10,440,588 | — |
| Charge for in-process research and development | — | 6,980,221 | — |
| Noncash portion of extraordinary items | (5,374,664) | 296,105 | — |
| Noncash charge related to asset impairment and cumulative effect of a change in accounting principle | 24,829,786 | — | — |
| Depreciation and amortization | 10,307,712 | 3,240,761 | 2,733,989 |
| Deferred income taxes | 26,257 | 418,815 | (69,311) |
| Other noncash items | 354,418 | 546,058 | — |
| Capital contribution from Inverness Medical Technology, Inc. related to income taxes for Inverness Medical, Inc. | — | 986,694 | 2,558,517 |
| Changes in assets and liabilities, net of acquisitions: | | | |
| Accounts receivable, net | 848,395 | 1,756,595 | (966,724) |
| Inventory | (2,201,566) | (223,137) | (619,960) |
| Prepaid expenses and other current assets | 467,666 | (1,817,441) | 627,429 |
| Accounts payable | 8,846,940 | (736,138) | 597,340 |
| Accrued expenses and other current liabilities | (10,362,494) | 15,095,696 | 1,684,817 |
| Due to Inverness Medical Technology, Inc. and affiliates | — | 2,649,018 | (455,037) |
| **Net cash provided by continuing operations** | 11,729,415 | 15,387,740 | 9,001,441 |
| **Net cash used in discontinued operations** | — | (1,170,123) | (1,293,325) |
| **Cash Flows from Investing Activities:** | | | |
| Purchases of property, plant and equipment | (6,077,140) | (3,593,715) | (863,791) |
| Proceeds from sale of property, plant and equipment | 1,544,666 | 140,849 | 83,000 |
| Cash paid for purchase of the Wampole Division of MedPointe Inc. | (70,607,942) | — | — |
| Cash paid for purchase of IVC Industries, Inc., net of cash acquired | (7,111,647) | — | — |
| Cash paid for purchase of Unipath business, net of cash acquired | (2,832,056) | (146,154,237) | — |
| Loan to Ostex International, Inc. | (1,000,000) | — | — |
| (Increase) decrease in other assets | (559,698) | 129,054 | 3,571 |
| **Net cash used in investing activities** | (86,643,817) | (149,478,049) | (777,220) |
| **Cash Flows from Financing Activities:** | | | |
| Cash paid for financing costs | (3,974,618) | (2,196,309) | (103,750) |
| Proceeds from issuance of common stock, net of issuance costs | 35,322,089 | 568,500 | — |
| Proceeds from issuance of preferred stock, net of issuance costs | 20,567,190 | 59,797,899 | — |
| Net proceeds received under revolving line of credit | 2,648,780 | — | — |
| Proceeds from borrowings under notes payable | 84,421,000 | 82,552,000 | 4,762,514 |
| Repayments of notes payable | (82,240,303) | (4,307,097) | (11,006,501) |
| Principal payments of capital lease obligations | (493,545) | — | — |
| Contribution from Inverness Medical Technology, Inc. | — | 47,659,616 | 1,969,054 |
| **Net cash provided by (used in) financing activities** | 56,250,593 | 184,074,609 | (4,378,683) |
| Foreign exchange effect on cash and cash equivalents | (2,691,392) | 137,877 | (141,293) |
| **Net (decrease) increase in cash and cash equivalents** | (21,355,201) | 48,952,054 | 2,410,920 |
| **Cash and cash equivalents, beginning of year** | 52,023,531 | 3,071,477 | 660,557 |
| **Cash and cash equivalents, end of year** | $ 30,668,330 | $ 52,023,531 | $ 3,071,477 |

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

## INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
## CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)

| | 2002 | 2001 | 2000 |
|---|---|---|---|
| **Supplemental Disclosure of Cash Flow Information:** | | | |
| Interest paid | $ 4,518,744 | $ 895,408 | $ 1,535,558 |
| Taxes paid | $ 2,728,121 | $ 45,458 | $ 30,000 |
| **Supplemental Disclosure of Noncash Activities:** | | | |
| Net assets of discontinued operations (Note 15(d)) | $ — | $ (19,400,109) | $ — |
| Long-term debt discharged as part of split-off from Inverness Medical Technology, Inc. (Note 1) | $ — | $ 8,084,126 | $ — |
| Forgiveness of amounts due to Inverness Medical Technology, Inc. and affiliates, net (Note 15(b)) | $ — | $ 10,368,735 | $ — |
| On September 20, 2002, the Company acquired the Wampole Division from MedPointe Inc. (Note 4(a))— | | | |
| Accounts receivable | $ 8,737,210 | $ — | $ — |
| Inventory | 4,923,756 | — | — |
| Other current assets | 967,664 | — | — |
| Property and equipment | 2,061,422 | — | — |
| Intangible assets | 56,301,472 | — | — |
| Accounts payable and accrued expenses | (1,491,524) | — | — |
| Cash paid for purchase of the Wampole Division | (70,607,942) | — | — |
| | 892,058 | — | — |
| Other accrued acquisition costs | (892,058) | — | — |
| Assumed liabilities | $ — | $ — | $ — |
| On March 19, 2002, the Company acquired IVC Industries, Inc. (Note 4(b))— | | | |
| Accounts receivable | $ 4,715,698 | $ — | $ — |
| Inventory | 9,831,608 | — | — |
| Property and equipment | 23,016,267 | — | — |
| Other assets | 1,755,173 | — | — |
| Accounts payable and accrued expenses | (12,495,423) | — | — |
| Cash paid for purchase of IVC Industries, Inc., net of cash acquired | (7,111,647) | — | — |
| | 19,711,676 | — | — |
| Other accrued acquisition costs | (1,053,967) | — | — |
| Fair value of assumed and issued fully-vested stock options | (1,298,674) | — | — |
| Assumed liabilities | $ 17,359,035 | $ — | $ — |
| On December 20, 2001, the Company acquired the Unipath business (Note 4(c))— | | | |
| Accounts receivable | $ — | $ 15,959,968 | $ — |
| Inventory | — | 13,066,918 | — |
| Other current assets | — | 2,369,472 | — |
| Property and equipment | — | 15,181,824 | — |
| Intangible assets | 484,384 | 134,522,691 | — |
| Cash paid for purchase of Unipath business, net of cash acquired | (2,832,056) | (146,154,237) | — |
| | (2,347,672) | 34,946,636 | — |
| Unfunded pension liability | 1,051,496 | (3,685,000) | — |
| Other accrued acquisition costs | 1,296,176 | (3,265,581) | — |
| Assumed liabilities | $ — | $ 27,996,055 | $ — |
| Dividends, interest and amortization of beneficial conversion feature related to preferred stock (Notes 11 and 12(b)) | $ 11,948,457 | $ — | $ — |
| Conversion of preferred stock to common stock (Note 12(b)) | $ 67,881,968 | $ — | $ — |

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

(1) Description of Business and Basis of Presentation

Inverness Medical Innovations, Inc. and its subsidiaries (the "Company") develop, manufacture and market consumer healthcare products, including self-test diagnostic products primarily for the women's health market and vitamins and nutritional supplements. The Company also develops, manufactures and distributes a wide variety of professional diagnostic products for use by medical and laboratory professionals.

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

The Company was incorporated on May 11, 2001 for the purpose of receiving IMT's contribution of its women's health, nutritional supplements and professional diagnostics businesses in connection with the transactions described in the Merger Agreement and related agreements. The Company's consolidated financial statements include IMT subsidiaries and businesses that were contributed to the Company for all periods presented as if such subsidiaries and businesses were historically organized in a manner consistent with the restructuring set forth in the Merger Agreement and related agreements. The primary subsidiaries and businesses that were contributed to the Company by IMT are as follows:

- Inverness Medical, Inc. ("IMI"), a U.S. corporation, and its wholly-owned subsidiary, Can-Am Care Corporation ("Can-Am"), a U.S. corporation
- Cambridge Diagnostics Ireland Ltd. ("CDIL"), an Irish corporation
- Orgenics, Ltd. ("Orgenics"), an Israeli corporation
- The women's health business of Inverness Medical Europe GmbH ("IME"), a German corporation
- Inverness Medical Benelux Bvba ("IMB"), a Belgian corporation
- The women's health assets held by IMT, plus allocations to the Company of IMT common expenditures

The Company has consolidated the financial statements of the above individual legal entities and the newly acquired entities and businesses, as discussed below, along with the assets, liabilities, revenues and expenses of the businesses. For all periods prior to the split-off and merger, the financial statements were combined in a manner consistent with the consolidated financial statements. All material intercompany transactions and balances have been eliminated. Amounts due to IMT and IMT affiliates that are not part of the Company are reflected as amounts due to Inverness Medical Technology, Inc. and affiliates. The Company's equity accounts for all periods presented reflect the par value of the Company's stock at the date of incorporation, effected for the fixed exchange ratio set forth in the Merger Agreement and related agreements and the related stock split (Note 2(k)); the

**(1) Description of Business and Basis of Presentation (Continued)**

historical equity accounts of the legal entities that comprise the Company are consolidated as if such subsidiaries and businesses were historically organized in a manner consistent with the restructuring set forth in the Merger Agreement and related agreements.

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

The discontinuation of the diabetes businesses is one of a number of transactions that occurred upon the closing of the transactions set forth in the Merger Agreement and related agreements that had a significant impact on the Company's financial statements. Prior to the split-off and merger, IMT capitalized the Company with approximately $41.4 million in cash in connection with the restructuring of the businesses as described herein. IMT also assumed or discharged all of the Company's third-party and related-party debt, except for the third-party debt maintained by CDIL and Orgenics. At the closing of the transactions set forth in the Merger Agreement and related agreements, IMT distributed to its stockholders one share of common stock of the Company for every five IMT shares held. In order for IMT to do so, the Company declared a stock split, which it effected as a dividend. Accordingly, earnings per share information for all periods presented represents the actual number of shares of the Company's common stock outstanding as of the date of its incorporation, effected for the fixed exchange ratio set forth in the Merger Agreement and related agreements and the related stock split (Notes 2(k) and 11).

The Company's consolidated financial statements for all periods prior to the split-off and merger also reflect the allocation of IMT's common expenditures. Such allocations have been made in accordance with Staff Accounting Bulletin ("SAB") No. 55, *Allocation of Expenses and Related Disclosure in Financial Statements of Subsidiaries, Divisions or Lesser Business Components of Another Entity.*

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

(1) Description of Business and Basis of Presentation (Continued)

reflect interest expense on amounts due to entities not included in the Company's consolidated financial statements (primarily to IMT) (Note 15(b)). Interest expense also reflects amounts recorded on third-party notes payable when such notes relate specifically to the Company's operations. Interest expense does not include amounts recorded on general corporate borrowings of IMT. The Company believes that the allocation methods described herein are reasonable and fairly reflect its financial position and results of operations.

Immediately prior to the split-off and merger, each IMT option or warrant was split into a new IMT option or warrant and a Company option or warrant (the new IMT options and warrants were subsequently converted into Johnson & Johnson options or warrants in the merger). The option or warrant split was accomplished in such a manner that the aggregate intrinsic value of the two options or warrants equals the intrinsic value of the IMT option or warrant before the split. The option or warrant split also required that the ratio of intrinsic value to market value for each option or warrant be the same. Accordingly, the total number of shares of common stock underlying stock options and warrants the Company issued in the split-off was 929,456 and 117,950, respectively. Concurrent with the option split, (1) the vesting for all Company options was accelerated and (2) the period of exercisability for IMT employees who did not become employees of the Company was extended. Such actions are deemed to be award modifications pursuant to Financial Accounting Standards Board ("FASB") Interpretation ("FIN") No. 44, *Accounting for Certain Transactions Involving Stock Compensation.* Under FIN No. 44, the Company measured compensation at the date of the award modifications based on the intrinsic value of the option and recognized (or will recognize in the future) such compensation if, absent the modifications, the award would have been forfeited pursuant to the award's original terms. For IMT employees who did not become employees of the Company, the recognition of this charge, or $644,505, was immediate and recorded as stock-based compensation expense in the accompanying consolidated statements of operations during 2001. For IMT employees who became Company employees, the Company has measured this potential charge, a maximum of $1,172,921, at the date of the modification, but will not record any such compensation charge unless and until such time as these Company employees terminate their employment with the Company. At such time, the portion of the award that, absent the modification, would have been forfeited under the award's original terms would be recognized as compensation expense. During 2002, the Company recognized stock-based compensation expense related to certain of the IMT employees who became Company employees in the amount of $120,748 as such employees terminated their employment with the Company.

Since the consummation of the split-off and merger, described above, the Company has completed a number of acquisitions, including its acquisition of the Wampole Division of MedPointe Inc. ("Wampole") on September 20, 2002, IVC Industries, Inc. ("IVC") on March 19, 2002 and certain entities, businesses and intellectual property of Unilever Plc (the "Unipath business") on December 20, 2001 (Note 4). Wampole markets and distributes point-of-care medical diagnostics products. IVC manufactures and distributes vitamins and nutritional supplements. The Unipath business develops, manufactures and distributes women's health and professional diagnostics products. The results of Wampole, IVC and the Unipath business are included in the consolidated financial statements of the Company since their respective acquisition dates.

**(2) Summary of Significant Accounting Policies**

*(a) Use of Estimates*

To prepare its financial statements in conformity with accounting principles generally accepted in the United States, the Company's management must make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from such estimates.

The Company considers the following to be critical accounting policies: (a) revenue recognition, (b) use of estimates for sales returns and other allowances and allowance for doubtful accounts, (c) valuation of inventory, (d) valuation of goodwill and other long-lived and intangible assets, (e) accounting for income taxes, and (f) legal contingencies.

*(b) Foreign Currencies*

The Company follows the provisions of SFAS No. 52, *Foreign Currency Translation*. All assets and liabilities of the Company's foreign subsidiaries are translated into U.S. dollars using the exchange rate at each balance sheet date while income and expense accounts are translated using the average rates of exchange during each reporting period. Foreign currency exchange transaction gains of $975,228 and losses of $727,357 and $388,832 during 2002, 2001 and 2000, respectively, are included as a component of other income (expense), net, in the accompanying consolidated statements of operations.

*(c) Cash and Cash Equivalents*

The Company considers all highly liquid investments purchased with original maturities of three months or less at the date of acquisition to be cash equivalents. Cash equivalents consisted of money market funds at December 31, 2002 and 2001.

*(d) Inventories*

Inventories are stated at the lower of cost (first-in, first-out) or market.

*(e) Depreciation and Amortization*

The Company records property, plant and equipment at historical cost or, in the case of a business combination, at fair value on the date of the business combination. Depreciation and amortization are computed using the straight-line method based on the following estimated useful lives of the related assets: machinery, laboratory equipment and tooling (3-16 years), leasehold improvements (lesser of term of lease or useful life of asset), buildings (20-39 years), furniture and fixtures (3-10 years) and computer equipment (3-5 years). Depreciation and amortization expense related to property, plant and equipment amounted to $6,363,709, $1,863,406 and $1,454,282 in 2002, 2001 and 2000, respectively.

*(f) Goodwill and Other Intangible Assets*

The Company has historically amortized goodwill that was generated from acquisitions prior to June 30, 2001 over the estimated useful life of such goodwill. On January 1, 2002, the Company adopted SFAS No. 142, *Goodwill and Other Intangible Asset,* and accordingly, no longer amortizes goodwill and other intangible assets with indefinite lives that were acquired prior to June 30, 2001 (Note 5). For goodwill acquired subsequent to June 30, 2001, the provisions of SFAS No. 142 were

(2) Summary of Significant Accounting Policies (Continued)

effective immediately. Also under SFAS No. 142, the Company performs annual impairment tests of the carrying value of its goodwill by reporting unit. During 2002, the Company recorded a goodwill impairment charge of $12,148,205 as a result of an independent appraisal of its nutritional supplement reporting unit (Note 5). The values assigned to the trade name that was acquired as part of the Wampole acquisition (Note 4(a)) and trademarks that were acquired as part of the Unipath business acquisition (Note 4(c)), have been assigned indefinite lives and therefore, in accordance with SFAS No. 142 are not being amortized..

The Company amortizes the trademarks related to the acquisition of certain nutritional supplement lines using the straight-line method over their estimated useful lives of 25 years. The intangible asset pertaining to the Company's acquired core immuno-assay technology (used in the women's health business) is being amortized over 15 years. The values assigned to patents and supplier relationships acquired as part of the acquisition of Wampole are being amortized over 13 and 10 years, respectively. The acquired intangible assets representing core technology and patents and license agreements related to the purchase of the Unipath business are being amortized over 13 and 7 years, respectively.

The following is a summary of goodwill and other intangible assets as of December 31, 2002:

| | Gross Carrying Amount | Accumulated Amortization |
|---|---|---|
| Amortized intangible assets: | | |
| Core technology and patents | $ 29,627,681 | $(3,822,884) |
| Supplier relationships | 11,020,000 | (306,081) |
| License agreements | 8,903,343 | (1,313,650) |
| Trademarks | 8,377,824 | (4,307,513) |
| | $ 57,928,848 | $(9,750,128) |
| Unamortized intangible assets: | | |
| Goodwill(i) | $108,914,675 | |
| Trademarks | 25,698,609 | |
| Trade name | 6,020,000 | |
| | $140,633,284 | |

(i) The company allocated $66,492,879 to its consumer products segment and $42,421,796 to its professional diagnostics segment.

(2) **Summary of Significant Accounting Policies (Continued)**

Amortization expense of intangible assets, which amounted to $3,944,003, $1,377,355 and $1,279,707 in 2002, 2001 and 2000, respectively, is included in cost of sales in the accompanying consolidated statements of operations. The following is a summary of estimated aggregate amortization expense of intangible assets for each of the five succeeding fiscal years as of December 31, 2002:

| | |
|---|---|
| 2003 | $4,932,973 |
| 2004 | 4,910,973 |
| 2005 | 4,742,973 |
| 2006 | 4,742,973 |
| 2007 | 4,742,973 |

*(g) Impairment of Long-Lived and Intangible Assets*

On January 1, 2002, the Company adopted SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, which addresses financial accounting and reporting for the impairment or disposal of long-lived assets. The Company examines on a periodic basis the carrying value of its long-lived and intangible assets to determine whether there are any impairment losses. If indicators of impairment were present in long-lived and intangible assets used in operations and undiscounted future cash flows were not expected to be sufficient to recover the assets' carrying amount, an impairment loss would be charged to expense in the period the impairment is identified based on the fair value of the asset. Accordingly, the Company recorded an impairment charge of $12,681,581 during 2002, related to trademarks and brand names of the Company's nutritional supplements business (Note 5). The Company believes that the remaining carrying values of its other long-lived and intangible assets were realizable as of December 31, 2002.

*(h) Income Taxes*

The Company follows the provisions of SFAS No. 109, *Accounting for Income Taxes*, under which deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities. Deferred tax assets and liabilities are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse (Note 13).

*(i) Revenue Recognition*

The majority of the Company's revenues are derived from product sales. The Company follows SAB No. 101, *Revenue Recognition,* which sets forth provisions for revenue recognition on multiple-element arrangements and acceptance and delivery criteria, among other items, and recognizes revenue when title has passed to the customer, less a reserve for estimated product returns and allowances.

To a lesser extent, the Company's revenues are derived from license and royalty fees from arrangements with third-party licensees. Revenue from fixed fee license and royalty agreements are recognized on a straight-line basis over the obligation period of such arrangements. License and royalty fees that are calculated based on the licensees' sales are recognized upon receipt of the license or royalty payments because these fees are not estimable until such time.

(2) Summary of Significant Accounting Policies (Continued)

*(j) Employee Stock-Based Compensation Arrangements*

The Company adopted an employee stock option plan in 2001 (Note 12(c)). For all periods presented in the accompanying financial statements the Company accounted for its employee stock-based compensation arrangements using the intrinsic value method under the provisions of APB Opinion No. 25, *Accounting for Stock Issued to Employees*, and FIN No. 44. The Company has elected to use the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, and SFAS No. 148, *Accounting for Stock-Based Compensation—Transition and Disclosure.* In addition, in accordance with FIN No. 44, the Company has included in these disclosures all IMT options held by those individuals who became the Company's employees at the time of the split-off and merger, retroactively converted into the Company's options as if such options had historically been granted by the Company (Note 12(c)).

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

| | 2002 | 2001 | 2000 |
|---|---|---|---|
| Net (loss) income—as reported | $(31,135,001) | $(24,730,887) | $2,181,821 |
| Stock-based employee compensation—as reported(a) | 10,268,342 | 9,796,082 | — |
| Pro forma stock-based employee compensation | (18,920,439) | (16,014,941) | (324,380) |
| Net (loss) income—pro forma | (39,787,098) | $(30,949,746) | $1,857,441 |
| Net (loss) income per basic and diluted share—as reported | $ (4.33) | $ (3.88) | $ 0.46 |
| Stock-based employee compensation—as reported | 1.03 | 1.54 | — |
| Pro forma stock-based employee compensation | (1.90) | (2.52) | (0.07) |
| Net (loss) income per basic and diluted share—pro forma | (5.20) | $ (4.86) | $ 0.39 |

(a) Stock-based employee compensation expense as reported represents the amortization of deferred compensation of certain stock options and restricted stock that were granted below fair market value.

The Company has computed the pro forma disclosures for stock options granted to employees after January 1, 1995 using the Black-Scholes option pricing model prescribed by SFAS No. 123. The assumptions used during each of the three years ended December 31, 2002 were as follows:

| | 2002 | 2001 | 2000 |
|---|---|---|---|
| Risk-free interest rate | 2.6-4.9% | 4.3-4.8% | 5.7% |
| Expected dividend yield | — | — | — |
| Expected lives | 5 years | 0.3-7 years | 5 years |
| Expected volatility | 58% | 54-82% | 82% |

The weighted average fair value under the Black-Scholes option pricing model of options granted to employees during 2002, 2001 and 2000 were $9.19, $10.35 and $8.39, respectively.

**(2) Summary of Significant Accounting Policies (Continued)**

*(k) Net (Loss) Income per Common Share*

Net (loss) income per common share, computed in accordance with SFAS No. 128, *Earnings per Share*, is based upon the actual number of common shares issued and outstanding upon incorporation of the Company, for all periods presented, effected for the fixed exchange ratio set forth in the Merger Agreement and related agreements and the related stock split (Notes 1 and 11).

The following table reconciles the number of IMT weighted average common shares outstanding for the periods prior to the split-off and merger, giving effect to the exchange ratio, to the Company's weighted average common shares used for the computation of net (loss) income per common share (Note 11).

| | 2001(i) | 2000 |
|---|---|---|
| Number of IMT weighted average shares | 31,814,360 | 23,631,949 |
| Exchange ratio to effect the exchange of IMT shares for the Company's shares 5:1 | 0.2 | 0.2 |
| Number of the Company's weighted average shares used for the computation of net (loss) income per common share in 2000 and 1999 | 6,362,872 | 4,726,390 |
| Weighted average shares issued after the split-off | 4,785 | |
| Number of the Company's weighted average shares used for the computation of net (loss) income per common share in 2001 | 6,367,657 | |

(i) IMT weighted average shares are through November 21, 2001, the date of split-off and merger.

*(l) Other Operating Expenses*

Shipping and handling costs, which amounted to $4,205,747, $1,216,302 and $939,688 in 2002, 2001 and 2000, respectively, are included in cost of sales in the accompanying consolidated statements of operations.

The Company expenses advertising costs as incurred. In 2002, 2001 and 2000, advertising costs amounted to $14,306,403, $354,278 and $184,536, respectively, and are included in sales and marketing expenses in the accompanying consolidated statements of operations.

*(m) Concentration of Credit Risk*

Financial instruments that potentially subject the Company to concentration of credit risk primarily consist of cash and cash equivalents and accounts receivable. The Company invests its excess cash primarily in high quality securities and limits the amount of its credit exposure to any one financial institution. The Company does not require collateral or other securities to support customer receivables; however, it performs ongoing credit evaluations of its customers and maintains allowances for potential credit losses.

The Company had an accounts receivable balance outstanding at December 31, 2002 from one customer, which represented 14% of its gross accounts receivable balance on that date. There were no accounts receivable balances outstanding at December 31, 2001 that were in excess of 10% of the gross

**(2) Summary of Significant Accounting Policies (Continued)**

accounts receivable balance on that date. There were no significant customers during 2002 that represented more than 10% of the Company's net revenues. During 2001 and 2000, the Company had another significant customer that represented 14% and 12% of its net revenues, respectively.

The Company has no significant off-balance-sheet or other concentration of credit risks such as foreign exchange contracts, option contracts or other foreign hedging arrangements at December 31, 2002 and 2001. In January 2003, the Company obtained an irrevocable letter of credit with its senior lender in the amount of $1,300,000 (Note 6(a)). See Note 14 for financial information by geographic area and business segment.

*(n) Financial Instruments and Fair Value of Financial Instruments*

The Company's primary financial instruments at December 31, 2002 and 2001 consisted of cash equivalents, accounts receivable and debt. The estimated fair value of these financial instruments approximates their carrying value at December 31, 2002 and 2001. The estimated fair values have been determined through information obtained from market sources. In February 2002, the Company entered into an interest rate swap agreement which protects it from interest rate fluctuations related to a portion of its senior long-term debt (Note 6(a)). Additionally, the Company's subsidiary in England enters into foreign currency exchange forward contracts from time to time to minimize its exposure to foreign currency exchange fluctuations because a substantial portion of its business is transacted in currencies other than its functional currency. At December 31, 2002, the Company had no foreign currency exchange forward contracts outstanding. The Company accounts for its derivative instruments in accordance with SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities*, and related amendments.

*(o) Recent Accounting Pronouncements*

In June 2001, the FASB issued SFAS No. 143, *Accounting for Asset Retirement Obligations*. This statement addresses the accounting and reporting for obligations associated with the retirement of tangible long-lived assets and the related asset retirement costs, in particular legal obligations associated with such retirement that result from the acquisition, construction, development and (or) the normal operation of a long-lived asset, except for certain obligations of lessees. The Company adopted this statement on January 1, 2003, as required. However, the adoption of this statement did not have a material impact on the Company's financial position, results of operations or cash flows.

In November 2001, the Emerging Issues Task Force ("EITF") issued EITF Issue No. 01-9, *Accounting for Consideration Given by a Vendor to a Customer or a Reseller of the Vendor's Products*. EITF Issue No. 01-9 establishes accounting and reporting standards for vendor consideration to any purchasers of the vendor's products at any point along the distribution chain, regardless of whether the purchaser receiving the consideration is a direct customer. The Company offers certain sales incentives that fall within the scope of EITF Issue No. 01-9, such as slotting fees and cooperative advertising, to some of its customers. The Company adopted the provisions of this consensus in 2002, the effect of which was reductions to net product sales in the amounts of $2,444,359 and $2,483,360 during 2001 and 2000, respectively, because of reclassifications from sales and marketing expenses for comparative purposes. These and certain other reclassifications impacting net product sales and cost of sales had no effect on loss or income from continuing operations or net loss or income in the respective years.

**(2) Summary of Significant Accounting Policies (Continued)**

In April 2002, the FASB issued SFAS No. 145, *Rescission of FASB Statements No. 4, 44 and 64 Amendment of FASB Statement No. 13 and Technical Corrections*, which addresses the reporting of gains and losses resulting from the extinguishment of debt, accounting for sale-leaseback transactions and rescinds or amends other existing authoritative pronouncements. SFAS No. 145 requires that any gain or loss on the extinguishment of debt that does not meet the criteria of APB Opinion No. 30 for classification as an extraordinary item shall not be classified as extraordinary and shall be included in earnings from continuing operations. The Company adopted the provisions of this statement on January 1, 2003. As a result, any gains and losses from early extinguishment of debt in the future will be included in earnings from continuing operations and all prior periods presented will be required to be restated. Consequently, the restatement of prior period losses upon the adoption of this statement will reduce the loss from continuing operations to $19.0 million, or $3.11 per basic and diluted share, in 2002 and increase the loss from continuing operations to $24.8 million, or $3.89 per basic and diluted share, in 2001.

In June 2002, the FASB issued SFAS No. 146, *Accounting for Costs Associated with Exit or Disposal Activities,* which addresses the recognition, measurement and reporting of costs associated with exit and disposal activities, including restructuring activities. This statement supersedes the guidance set forth in EITF Issue No. 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring).* SFAS No. 146 requires that a liability for a cost associated with an exit or disposal activity only be recognized when the liability is incurred, while under the previous guidance of EITF Issue No. 94-3, such liability would have been recognized at the date of an entity's commitment to an exit plan. This statement also establishes that fair value should be used for initial measurement of the liability. However, this statement does not apply to costs associated with exit activities that involve an entity newly acquired in a business combination. The Company is required to apply the guidance of SFAS No. 146 with respect to exit or disposal activities initiated after December 31, 2002. Under current operating plans, the Company does not expect the adoption of this statement to have a material impact on its financial position, results of operations or cash flows.

In November 2002, the FASB issued FIN No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, which will significantly change current practice in the accounting for, and disclosure of, guarantees. FIN No. 45 requires that a guarantor recognize, at the inception of certain types of guarantees, a liability of the obligation undertaken in issuing the guarantee at fair value. The interpretation also requires significant new disclosures in the financial statements of the guarantor about its obligations under certain guarantees. The Company is required to apply the disclosure provisions of FIN No. 45 in its financial statements as of December 31, 2002. The accounting provisions of FIN No. 45 are applicable for guarantees issued or modified after December 31, 2002. The disclosure requirements of FIN No. 45 did not have a material effect on the Company's financial statements and the Company does not expect the accounting provisions of this interpretation to have a material impact on its financial position, results of operations or cash flows.

(2) Summary of Significant Accounting Policies (Continued)

In December 2002, the FASB issued SFAS No. 148. This statement amends SFAS No. 123, *Accounting for Stock-Based Compensation,* to provide alternative methods of transition to SFAS No. 123's fair value method of accounting for stock-based employee compensation. SFAS No. 148 also amends the disclosure provisions of SFAS No. 123 and APB Opinion No. 28, *Interim Financial Reporting,* to require expanded disclosure of the effects of a company's accounting policy for stock-based employee compensation. The statement does not require companies to account for employee stock options using the fair value method. The Company adopted the disclosure provisions of SFAS No. 148 as of December 31, 2002, as required; however, the Company will continue to account for employee stock options using the intrinsic value method under APB Opinion No. 25, as permitted.

*(p) Reclassifications*

Certain prior-year account balances have been reclassified to be consistent with the current year's presentation.

**(3) Other Balance Sheet Information**

Components of selected captions in the consolidated balance sheets consist of:

| | December 31, | |
|---|---|---|
| | 2002 | 2001 |
| Inventories: | | |
| Raw materials | $13,447,077 | $ 5,476,722 |
| Work-in-process | 7,075,549 | 2,451,736 |
| Finished goods | 16,631,772 | 6,853,532 |
| | $37,154,398 | $14,781,990 |
| Property, plant and equipment: | | |
| Machinery, laboratory equipment and tooling | $34,749,911 | $14,640,938 |
| Leasehold improvements | 6,094,040 | 4,899,956 |
| Buildings | 8,725,874 | 676,843 |
| Furniture and fixtures | 2,119,611 | 1,448,687 |
| Computer equipment | 4,741,490 | 3,324,296 |
| | 56,430,926 | 24,990,720 |
| Less—Accumulated depreciation and amortization | 10,630,837 | 4,464,492 |
| | $45,800,089 | $20,526,228 |
| Trademarks and trade name with indefinite lives: | | |
| Trademarks | $25,698,609 | $25,698,609 |
| Trade name | 6,020,000 | — |
| | $31,718,609 | $25,698,609 |

(3) **Other Balance Sheet Information (Continued)**

| | December 31, 2002 | December 31, 2001 |
|---|---|---|
| **Other intangible assets:** | | |
| Supplier relationships | $11,020,000 | $ — |
| License agreements | 8,903,343 | 8,903,343 |
| Trademarks | 8,377,824 | 21,059,405 |
| | 28,301,167 | 29,962,748 |
| Less—Accumulated amortization | 5,927,244 | 4,136,639 |
| | $22,373,923 | $25,826,109 |
| **Accrued expenses and other current liabilities:** | | |
| Advertising and marketing | $ 9,298,463 | $10,324,041 |
| Compensation and compensation-related | 8,850,820 | 4,840,278 |
| Professional fees | 5,687,887 | 2,221,353 |
| Due to Inverness Medical Technology, Inc. | 3,018,052 | 11,990,786 |
| Other | 13,526,242 | 13,340,310 |
| | $40,381,464 | $42,716,768 |

(4) **Business Combinations**

*(a) Acquisition of Wampole*

On September 20, 2002, the Company acquired Wampole, a distributor of professional diagnostic and point-of-care medical diagnostic products primarily in the United States (Note 1). This acquisition allows the Company to expand its business in the point-of-care market in the United States and provides the Company with certain intellectual property. The aggregate purchase price of Wampole is estimated at $71,500,000, which consisted of $69,921,000 in cash and $1,579,000 in estimated direct acquisition costs. The acquisition was funded by the issuance of $35,000,000 in subordinated debt (Notes 6(b) and (c)) and a portion of the Company's existing cash at the time of the acquisition. The aggregate purchase price for Wampole was preliminarily allocated to the acquired assets and assumed liabilities as follows:

| | |
|---|---|
| Accounts receivable | $ 8,737,210 |
| Inventory | 4,923,756 |
| Property, plant and equipment | 2,061,422 |
| Goodwill | 35,361,472 |
| Trade name | 6,020,000 |
| Patents | 3,900,000 |
| Supplier relationships | 11,020,000 |
| Other assets | 967,664 |
| Accounts payable and accrued expenses | (1,491,524) |
| | $71,500,000 |

(4) Business Combinations (Continued)

The above allocation of the aggregate purchase price for Wampole to the acquired intangible assets is based upon a preliminary independent appraisal. Changes in estimated direct acquisition costs could impact the aggregate purchase price and its allocation to net assets acquired.

The acquisition of Wampole is accounted for as a purchase under SFAS No. 141, *Business Combinations*. Accordingly, the results of Wampole have been included in the accompanying consolidated financial statements since the acquisition date as part of the Company's professional diagnostic products reporting unit and business segment. The Company has assigned indefinite lives to the acquired goodwill and trade name. The value of such goodwill is fully deductible for tax purposes over 15 years; because goodwill is no longer amortized for book purposes, the tax amortization of the goodwill gives rise to a deferred tax liability as of December 31, 2002. The values allocated to the acquired patents and supplier relationships are being amortized on a straight-line basis over their estimated useful lives of 13 and 10 years, respectively. The weighted average amortization period for the acquired intangible assets with finite lives is estimated to be 10.8 years.

*(b) Acquisition of IVC*

On March 19, 2002, the Company acquired IVC, a manufacturer and distributor of vitamins and nutritional supplements primarily in the United States (Note 1). With the addition of IVC, the Company was able to consolidate certain of its vitamin and nutritional supplement manufacturing at IVC and discontinue most of its outsourced manufacturing arrangements. The aggregate purchase price of IVC was $27,299,679, which consisted of $5,619,493 in cash representing $2.50 for each outstanding share of IVC's common stock, fully-vested stock options to purchase an aggregate of 115,744 shares of the Company's common stock, which options had an aggregate fair value of $1,298,674, calculated using the Black-Scholes option pricing model, $1,586,657 in costs to exit certain activities of IVC, primarily severance costs of involuntarily terminated employees in accordance with EITF Issue No. 95-3, *Recognition of Liabilities in Connection with a Purchase Business Combination*, $17,359,035 in assumed debt and $1,435,820 in direct acquisition costs. The acquisition was funded by the Company's existing cash. The aggregate purchase price for IVC was allocated to the acquired assets and assumed liabilities as follows:

| | |
|---|---|
| Cash and cash equivalents | $ 476,356 |
| Accounts receivable | 4,715,698 |
| Inventory | 9,831,608 |
| Property, plant and equipment | 23,016,267 |
| Other assets | 1,755,173 |
| Accounts payable and accrued expenses | (12,495,423) |
| | $ 27,299,679 |

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

**(4) Business Combinations (Continued)**

Immediately after the close of the acquisition, the Company reorganized the business operations of IVC to improve efficiencies and eliminate redundant activities on a company-wide basis. The restructuring affected all cost centers within the organization, but most significantly responsibilities at the sales and executive levels, as such activities were combined with the Company's existing business operations. In addition, the Company is in the process of relocating one of IVC's warehouses to a closer proximity of the manufacturing facility to improve efficiency. The warehouse relocation is expected to commence by the end of March 2003. Of the $1,586,657 in total exit costs, which include severance costs of involuntarily terminated employees and costs to vacate the warehouse, $532,690 has been paid and $1,053,967 remained unpaid as of December 31, 2002. The total number of involuntarily terminated employees was 47, of which 3 remained to be terminated as of December 31, 2002.

*(c) Acquisition of the Unipath Business*

On December 20, 2001, the Company acquired the Unipath business from Unilever Plc ("Unilever") (Note 1). The Unipath business, with its core operations based in England, develops, manufactures and distributes home pregnancy and ovulation testing and natural family planning products that are sold worldwide. Together with the acquisition of the Unipath business, the Company also acquired rights to certain antibody clones and other intellectual property. The Unipath business provides the Company with leading brand name consumer diagnostic products that compliment the Company's existing value branded and private label home pregnancy detection and ovulation prediction products.

The aggregate purchase price for the Unipath business of $158,618,966 consisted of $146,490,374 in cash, $4,159,458 in costs to exit certain activities of the acquired business, primarily severance costs in accordance with EITF Issue No. 95-3, estimated unfunded pension liability of $2,633,504 upon the assumption of the pension benefits of the acquired employees based in England and $5,335,630 in direct acquisition costs. The acquisition was funded by the issuance of 1,995,000 shares of series A convertible redeemable preferred stock ("Series A Preferred Stock") with aggregate proceeds of $59,850,000 (Note 12(b)), $62,500,000 in loans under a series of credit agreements with a bank and entities related to this bank (Note 6(f)), the issuance of subordinated promissory notes and warrants for aggregate proceeds of $20,000,000 (Note 6(g)) and the Company's existing cash.

(4) Business Combinations (Continued)

The aggregate purchase price of the Unipath business was allocated to the acquired assets and assumed liabilities as follows:

| | |
|---|---|
| Cash and cash equivalents | $ 5,029,764 |
| Accounts receivable | 15,959,968 |
| Inventory | 13,066,918 |
| Other current assets | 2,369,472 |
| Property and equipment | 15,181,824 |
| Goodwill and trademarks | 99,051,814 |
| In-process research and development | 6,980,221 |
| Core technology and patents | 20,071,697 |
| License agreements | 8,903,343 |
| Liabilities assumed | (27,996,055) |
| | $158,618,966 |

The acquisition of the Unipath business was accounted for as a purchase under SFAS No. 141. Accordingly, the results of the Unipath business have been included in the accompanying consolidated financial statements since the acquisition date and are primarily included in the Company's women's health reporting unit within the consumer products business segment. To a much lesser extent, the results of the Unipath business are included in the Company's professional diagnostics business segment. The allocation of the purchase price to the assets acquired is based upon the results of an independent appraisal of the fair value of the assets. The Company is amortizing the portion of the purchase price allocated to certain intangible assets with finite lives, which are comprised of core technology and patents and license agreements, on a straight-line basis over their estimated useful lives of 13 and 7 years, respectively. The weighted average amortization period for these assets is 11.2 years. The acquired goodwill, the majority of which is not deductible for tax purposes, and trademarks are assigned indefinite lives.

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 in-process research and development project ("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 $6,980,221, was charged to expense upon the acquisition. The amount of the purchase price allocated to this IPRD Project represents its estimated fair value determined using the income approach, whereby projected future cash flows are 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. Management believes that many of the complex technical issues have been resolved; however, the technology does not have Food and Drug Administration approval. Therefore, the risk of not achieving commercialization is not only a developmental risk, but a regulatory risk as well. The work of a full project, which includes demonstrating feasibility, defining the project, design, development, verification and clinical testing, and regulatory submission and approval, will need to be completed prior to a launch of a product based on this technology. As these hurdles are crossed, new complexities are likely to arise. The Company initially anticipated that this IPRD Project would take one to one and a half years from the acquisition

(4) **Business Combinations (Continued)**

date to complete and the current estimate of the completion date remains unchanged. During the initial valuation of the project the Company estimated that it would cost approximately $2,700,000 in additional research and development costs to complete this IPRD Project. Since then, the Company has incurred approximately $903,000 in research and development costs through December 31, 2002 and currently expects estimated costs to complete to be approximately $988,000. The reduction in research and development costs from the original estimate is due to the Company's subsequent decision to change the outsourced prototype tooling and design work from a contractor in Europe to one in China. Based upon time and costs incurred, this IPRD Project was estimated to be approximately 97% complete as of December 31, 2002.

As a result of the business combination, the Company reorganized the operations of the Unipath business for purposes of improving efficiencies and achieving economies of scale on a company-wide basis. Such reorganization affected all major cost centers at the operations in England. Additionally, most business activities of the U.S. division were merged into the Company's existing U.S. businesses. The total number of involuntarily terminated employees was 65, all of which have been terminated as of December 31, 2002. Total exit costs, which primarily related to severance, were initially estimated at $2,340,544. During 2002, the Company finalized all restructuring activities and recorded an additional $1,818,914 in exit costs. The additional exit costs were recorded as adjustments to the Unipath purchase price. As of December 31, 2002, $1,217,743 in exit costs remained unpaid.

As part of the acquisition of the Unipath business, the Company agreed to establish a new pension plan for the acquired employees based in England (the "UK Employees"). The Company's new pension plan will cover the UK Employees during the remainder of the three year post-acquisition period and the UK Employees may also elect, at their option, to transfer contributions and benefits from the Unilever pension plan to the Company's new plan. The Company's new pension plan will be no less favorable to the UK Employees than Unilever's plan and the Company will maintain this benefit for a period of at least three years from the acquisition date. Accordingly, pursuant to SFAS No. 87, *Employer's Accounting for Pensions*, and SFAS No. 88, *Employer's Accounting for Settlements and Curtailments of Defined Benefit Pension Plans and for Termination Benefits*, the Company recorded an unfunded pension liability of $3,685,000 as part of the purchase price on the acquisition date. Such unfunded pension liability represented the excess of the projected benefit obligation, or $20,485,000, over the fair value of the plan assets, or $16,800,000, that was initially allocated by Unilever to the pension benefits for the UK Employees. As some of the UK Employees were involuntarily terminated under the Company's restructuring plan, the unfunded pension liability initially recorded by the Company was reduced by the portion of their severance pay-out that related to pension benefits, or $1,051,496, which was reclassified to severance costs for purposes of aggregating the purchase price. As of December 31, 2002, the number and identities of UK employees who may elect to transfer to the Company's new pension plan are unknown. In addition, Unilever and the Company have not yet fully agreed on all of the terms of the Company's new pension plan, which could affect the amount of funding required by the Company. Therefore, the unfunded pension obligation of the Company for such UK Employees, if any, who will elect to participate in and transfer their pension assets from Unilever's pension plan to the Company's new pension plan, was not estimable. As a result, the remaining pension liability of $2,633,504 at December 31, 2002, which is included in other liabilities in the accompanying consolidated balance sheet, will be adjusted upon the election by the UK Employees to transfer to the Company's new pension plan, if any. The Company will record such adjustment to the aggregate purchase price, and accordingly, the balance of goodwill will be adjusted.

(4) Business Combinations (Continued)

*(d) Pro Forma Financial Information*

The following table presents selected unaudited financial information of the Company, including Wampole, IVC and the Unipath business as if the acquisitions of these entities had occurred on January 1, 2001. The unaudited pro forma results of 2001 exclude a charge to operations of $6,980,221, which represents the portion of the purchase price allocated to the fair value of an in-process research and development project related to the acquisition of the Unipath business. The unaudited pro forma results are not necessarily indicative of the results that would have occurred had the acquisitions of Wampole, IVC and the Unipath business been consummated on January 1, 2001, respectively, or future results.

| | 2002 | 2001 |
|---|---|---|
| | (unaudited) | |
| Pro forma net revenue | $249,945,276 | $257,615,925 |
| Pro forma loss from continuing operations | (24,244,377) | (24,852,164) |
| Pro forma net loss | (31,262,594) | (25,120,849) |
| Pro forma loss per common share: | | |
| Pro forma loss from continuing operations | $ (3.64) | $ (3.90) |
| Pro forma net loss | (4.35) | (3.94) |

*(e) Pending Merger with Ostex International, Inc.*

On September 6, 2002, the Company entered into an agreement and plan of merger with Ostex International, Inc. ("Ostex"), pursuant to which the Company intends to acquire Ostex. Ostex develops and commercializes osteoporosis diagnostic products. The pending acquisition of Ostex is subject to several closing conditions, including approval of the merger agreement governing the acquisition by Ostex's shareholders and the Company's receipt of any necessary consents with respect to the transactions contemplated by the merger agreement required under any of the Company's material loan agreements. On February 18, 2003, in order to increase the likelihood that the Company would obtain the consent to the merger from the Company's senior lender, as required under the Company's material loan agreements (Note 6(a)), the parties amended the merger agreement to reduce the amount of consideration to be paid to acquire Ostex. Under the merger agreement, as amended, the aggregate number of shares of the Company's common stock to be issued in the merger for Ostex's outstanding shares and to be reserved for the options and warrants to be assumed by the Company is 1,900,000 shares. Under the amended merger agreement, at the effective time of the merger, each outstanding share of Ostex common stock shall be converted into the right to receive a number of shares of the Company's common stock equal to a conversion ratio that is to be calculated by dividing 1,900,000 by the sum of (1) the total number of shares of Ostex common stock outstanding immediately prior to the effective time of the merger, and (2) the total number of shares of Ostex common stock subject to outstanding stock options and warrants that the Company is to assume in the merger. The shares of Ostex common stock subject to options and warrants to be assumed by the Company will convert at the same ratio. The merger remains subject to approval by the holders of two thirds of Ostex's outstanding voting stock, so there can be no assurance that the Company's acquisition of Ostex will occur.

(4) **Business Combinations (Continued)**

Also as part of the merger transaction with Ostex, the Company entered into a loan agreement to lend Ostex up to $2,000,000 to support their operations prior to the effective time of the merger. As of December 31, 2002, aggregate outstanding loans to Ostex amounted to $1,000,000, which loans bear interest per annum ranging from 6.04% to 6.27%. The loans mature on the earliest of (i) the acceleration of the loans by the Company upon the occurrence of an event of default, as defined in the merger agreement, (ii) termination of the merger agreement under certain specified circumstances, or (iii) December 31, 2003. The aggregate outstanding balance of the loans to Ostex is included as a component of prepaid expenses and other current assets in the accompanying balance sheet.

As of December 31, 2002, the Company has incurred $750,192 in acquisition costs related to the proposed merger with Ostex, which have been deferred and included in deferred financing costs and other assets, net, in the accompanying balance sheet.

(5) **Goodwill and Other Intangible Assets**

On January 1, 2002, the Company adopted SFAS No.142, which addresses changes in the financial accounting and reporting for acquired goodwill and other intangible assets with indefinite lives. As a result, the Company no longer records amortization of goodwill. During both 2001 and 2000, the Company recorded amortization expense, net of taxes, of $398,112 related to goodwill. This amortization expense was allocated to general and administrative expenses in the accompanying consolidated statements of operations. The following table presents the (loss) income from continuing operations and net (loss) income of the Company, as if SFAS No. 142 was adopted for the prior periods presented:

| | 2001 | 2000 |
|---|---|---|
| (Loss) income from continuing operations | $(24,462,202) | $2,779,605 |
| Add back: Goodwill amortization, net of tax | 398,112 | 398,112 |
| Adjusted (loss) income from continuing operations | $(24,064,090) | $3,177,717 |
| Net (loss) income | $(24,730,887) | $2,181,821 |
| Add back: Goodwill amortization, net of tax | 398,112 | 398,112 |
| Adjusted net (loss) income | $(24,332,775) | $2,579,933 |
| **Adjusted (loss) income per common share—basic and diluted:** | | |
| Adjusted (loss) income from continuing operations | $ (3.78) | $ 0.67 |
| Adjusted net (loss) income | $ (3.82) | $ 0.55 |

SFAS No. 142 also provides specific guidance for determining and measuring impairment of goodwill. Based upon the results of an independent impairment review, as required by SFAS No. 142, the Company recorded an impairment charge of $12,148,205, representing the remaining goodwill related to its reporting unit that comprises the nutritional supplement lines the Company acquired in 1997. This amount represented the excess of the carrying value over the fair value of such asset. The fair value was determined using a combination of the income approach and the market approach of valuing a business. The income approach valued the business by discounting projected future cash flows and the market approach valued the security underlying the business by comparing it to those of similar

(5) Goodwill and Other Intangible Assets (Continued)

businesses. The most significant facts and circumstances that led to the conclusion of this impairment were (a) future cash flows from these nutritional supplement lines are expected to be reduced, (b) selling, general and administrative expenses relating to these nutritional supplement lines are forecasted to increase as a percentage of sales, and (c) the nutritional supplements business is experiencing a larger percentage decline in revenues than most of the comparable businesses of other companies. This impairment charge was recorded in the first quarter of 2002 and classified in accordance with SFAS No. 142 as a cumulative effect of a change in accounting principle in the accompanying statements of operations.

Because the independent appraisal of the fair value of the reporting unit underlying the Company's nutritional supplements business indicated a goodwill impairment of that reporting unit, as discussed above, the Company proceeded to also obtain an independent impairment review of the carrying value assigned to related trademarks and brand names in accordance with SFAS No. 144. The results of the impairment review under SFAS No. 144 indicated an impairment of the carrying value of such trademarks and brand names because the full carrying amount of these intangible assets was not expected to be recoverable and exceeded its fair value. The carrying amount of these intangible assets was not recoverable because it exceeded the sum of the undiscounted cash flows expected to result from the use and eventual disposition of these assets. The fair value of these intangible assets was determined using a combination of the discounted cash flow approach and the relief from royalty approach, the latter of which valued the trademarks as if they were licensed from a third party. Based on these results, the Company recorded an impairment charge of $12,681,581 during the first quarter of 2002, which was included in operating expenses in the accompanying statements of operations. The remaining carrying value of these intangible assets was $4,070,312 at December 31, 2002, which is being amortized over the average remaining useful life of the intangible asset of 19 years.

(6) Long-term Debt

The Company had the following long-term debt balances outstanding:

| | December 31, | |
|---|---|---|
| | 2002 | 2001 |
| Senior credit facilities | $ 52,960,000 | $ — |
| 10% Subordinated notes | 18,856,106 | — |
| 9% Subordinated notes | 9,000,000 | — |
| 3% Convertible notes | 6,000,000 | — |
| IVC credit facilities | 11,741,679 | — |
| Bonds payable | 2,655,005 | — |
| Term loans and revolving line of credit | — | 61,145,997 |
| Subordinated bridge notes | — | 16,511,390 |
| Other | 520,711 | 466,830 |
| | 101,733,501 | 78,124,217 |
| Less: Current portion | 17,200,390 | 20,819,383 |
| | $ 84,533,111 | $57,304,834 |

**(6) Long-term Debt (Continued)**

The following describes each of the above listed debt instruments:

*(a) Senior Credit Facilities*

On November 14, 2002, the Company and certain of its subsidiaries entered into a senior credit agreement with a group of banks for credit facilities in the aggregate amount of up to $55,000,000. The senior credit agreement consists of a U.S. term loan of $20,000,000, a European term loan of $10,000,000 and a European revolving line of credit of up to $25,000,000. Aggregate initial borrowings amounted to $30,000,000 under the term loans and $22,960,000 under the revolving line of credit upon the execution of the senior credit agreement, which remained outstanding as of December 31, 2002. The unused portion of the revolving line of credit was $2,040,000 at December 31, 2002, the availability of which was restricted by $160,970 due to the banks' guarantee of a value added tax bond issued on behalf of the Unipath business in England. Subsequently, on January 8, 2003, an irrevocable letter of credit in the amount of $1,300,000 was issued on behalf of the Company, which then further restricts the availability of the revolving line of credit for that amount. The letter of credit expires on June 30, 2003 and is automatically renewable for periods of one year from each future expiration date.

Principal repayments under the U.S. term loan are to be made in 11 equal quarterly installments of $1,250,000 commencing on April 30, 2003 through October 31, 2005 with a final installment of $6,250,000 due on November 14, 2005. Principal repayments under the European term loan are to be made in 14 equal quarterly installments of $25,000 starting on January 31, 2003 through April 30, 2006 with a final installment of $9,650,000 due on May 14, 2006. The Company may also choose to prepay all or part of the term loans provided that it prepays at least $1,000,000 or a multiple thereof. The Company may repay borrowings under the revolving line of credit at any time but in no event later than November 14, 2005. The Company is required to make mandatory prepayments on the loans under the senior credit agreement if it meets certain cash flow thresholds, collects certain insurance proceeds in excess of certain thresholds, issues equity securities on or after November 14, 2003 or sells assets not in the ordinary course of its business.

Borrowings under the term loans and the revolving line of credit bear interest at either (i) the London Interbank Offered Rate ("LIBOR"), as defined, plus applicable margins or, at the Company's option, (ii) a floating Index Rate, as defined, plus applicable margins. Applicable margins, depending on the type of loan, can range from 1.25% to 3.75% and are subject to quarterly adjustments based on the Company's total leverage ratio, as defined. At December 31, 2002, the interest rates of the U.S. term loan, the European term loan and the revolving line of credit were 6.25%, 6.75% and 6.25%, respectively. The Company recorded interest expense, including amortization of deferred financing costs, under these credit facilities in the aggregate amount of $521,494 in 2002.

Borrowings under the senior credit facilities are secured by the stock of certain of the Company's U.S. and European subsidiaries, a significant portion of the Company's intellectual property rights and the assets of the Company's business in the U.S. and Europe, excluding those assets of IVC, Orgenics Ltd., the Company's Israeli subsidiary, and Unipath Scandinavia AB, the Company's Swedish subsidiary. Under the senior credit agreement, the Company must comply with various financial and non-financial covenants. The primary financial covenants pertain to, among other things, fixed charge coverage ratio, capital expenditure, various leverage ratios, earnings before interest, taxes, depreciation and amortization ("EBITDA") and minimum cash requirement. Additionally, the senior credit

(6) Long-term Debt (Continued)

agreement currently prohibits the payment of dividends. As of December 31, 2002, the Company was in compliance with the covenants.

Upon receipt of the proceeds from the loans under the senior credit agreement, $44,110,860 was used to prepay the outstanding principal balance and any accrued and unpaid interest on the term loans and line of credit under a series of credit agreements (Note 6(f)).

*(b) Subordinated Promissory Notes, 10%, Principal Amount $20,000,000*

On September 20, 2002, the Company sold units ("Units") having an aggregate purchase price of $20,000,000 to private investors to help finance the Wampole acquisition (Note 4(a)). Each Unit consisted of (i) a 10% subordinated promissory note (a "10% Subordinated Note") in the principal amount of $50,000 and (ii) a warrant to acquire 400 shares of the Company's common stock at an exercise price of $13.54 per share. In the aggregate, the Company issued fully vested warrants to purchase 160,000 shares of its common stock, which may be exercised at any time on or prior to September 20, 2012. Interest accrues at 10% per annum, compounded daily, on the outstanding principal amount and 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 the Company may prepay the 10% Subordinated Notes at any time, subject to certain prepayment penalties. The Company may, at its option, repay the 10% subordinated notes and pay any prepayment penalty, if applicable, in cash or in shares of its 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 $150,000,000 of indebtedness for borrowed money incurred or guaranteed by the Company plus any other indebtedness that the Company incurs to finance an acquisition.

The Company allocated $1,200,000 of the principal amount of the 10% Subordinated Notes to the warrants as original issue discount, which represented the fair value of the warrants at the date of issuance. In addition, the placement agent for the offering of the 10% Subordinated Notes received cash commissions and an expense allowance totaling $970,421 and a warrant to purchase 37,700 shares of the Company's common stock, the terms of which are identical to the warrants sold as part of the Units. The value of the warrant issued to the placement agent, $302,008, and the cash commission and expense allowance are recorded as deferred financing costs. The original issue discount related to the warrants issued to the subscribers and the deferred financing costs are being amortized to interest expense over the six year term of the 10% Subordinated Notes. Interest expense, including amortization of original issue discount and deferred financing costs, related to the 10% Subordinated Notes was $692,764 in 2002.

Among the purchasers of the 10% Subordinated Notes were three directors and officers of the Company and an entity controlled by the Company's chief executive officer, who collectively purchased an aggregate of 37 Units, or $1,850,000 in aggregate principal amount, and warrants to purchase an aggregate of 14,800 shares of the Company's common stock.

**(6) Long-term Debt (Continued)**

*(c) Subordinated Promissory Notes, 9%,Principal Amount $9,000,000, and Convertible Subordinated Promissory Notes, 3%, Principal Amount $6,000,000*

On September 20, 2002, also in connection with the financing of the Wampole acquisition (Note 4(a)), the Company sold subordinated promissory notes in an aggregate principal amount of $9,000,000 (the "9% Subordinated Notes") and subordinated convertible promissory notes in an aggregate principal amount of $6,000,000 (the "3% Convertible Notes") to private investors. The 9% Subordinated Notes and 3% Convertible Notes bear interest at 9% and 3% per annum, respectively, on the outstanding principal balance and are payable quarterly in arrears on the first day of each calendar quarter starting October 1, 2002. The Company recorded interest expense, including amortization of deferred financing costs, on these notes of $282,192 in 2002. Both the 9% Subordinated Notes and the 3% Convertible Notes mature on September 20, 2008, subject to acceleration in certain circumstances, and the Company may prepay the 9% Subordinated Notes at anytime, subject to certain prepayment penalties. Upon maturity, the Company has the option to repay the notes and pay any prepayment penalty, if applicable, in cash or in shares of its 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, holders of the 3% Convertible Notes have the option to convert all of their outstanding principal amounts and unpaid interest into the Company's common stock at a conversion price equal to $17.45 per share, which was 125% of the average closing price of the Company's common stock over the ten consecutive trading days ending two days prior to September 20, 2002. Additionally, the outstanding principal amount and unpaid interest on the 3% Convertible Notes will automatically convert into the Company's common stock at a conversion price equal to $17.45 if, at any time after September 20, 2004, the average closing price of the Company's common stock in any consecutive thirty-day period is greater than $22.67.

The 9% Subordinated Notes and 3% Convertible Notes are expressly subordinated to up to $150,000,000 of indebtedness for borrowed money incurred or guaranteed by the Company plus any other indebtedness the Company incurs to finance an acquisition, provided that the 9% Subordinated Notes and 3% Convertible Notes rank equally with each other and with the 10% Subordinated Notes.

An entity controlled by the Company's chief executive officer purchased 3% Convertible Notes in the aggregate principal amount of $3,000,000.

*(d) IVC Credit Facilities*

In connection with the acquisition of IVC, the Company assumed IVC's borrowings under a senior credit agreement ("IVC Credit Agreement"). Pursuant to the IVC Credit Agreement, as amended, IVC can borrow up to $15,000,000 under a revolving credit commitment and $4,200,000 under a term loan commitment, subject to specified borrowing base limitations. As of December 31, 2002, IVC had $8,532,794 in outstanding borrowings under the revolving credit commitment and $3,208,885 in outstanding principal amount under the term loan. Borrowings under the IVC Credit Agreement will mature on October 16, 2003. Borrowings under the revolving credit commitment and the term loan bear interest at either 1.50% above the bank's prime rate or, at IVC's option, at 3.75% above the Adjusted Eurodollar Rate used by the bank. At December 31, 2002, the interest rates on the loan facilities ranged from 4.65% to 5.75%. Interest expense, including amortization of deferred financing costs, on IVC's credit facilities was $660,547 in 2002.

(6) Long-term Debt (Continued)

The notes are collateralized by substantially all of IVC's assets. The IVC Credit Agreement requires IVC 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, 2002, IVC was in compliance with such requirements and restrictions.

*(e) Bonds Payable*

Also in connection with the acquisition of IVC, the Company assumed IVC's bonds payable, which had an aggregate outstanding balance of $2,655,005 as of December 31, 2002. The bonds are payable in various installments through June 30, 2007 and the majority of the bonds payable balance bear interest at 6.90%. Interest on the majority of the bonds payable balance is payable semi-annually and IVC recorded interest expense, including amortization of deferred financing costs, on such bonds of $214,006 during 2002. The bonds are collateralized by certain property and equipment of IVC. Additionally, the bonds require IVC to maintain letters of credit from a bank equal to the outstanding principal balances of the bonds and the fees on the letters of credit range from .75% to 3% per annum.

*(f) Term Loans and Revolving Line of Credit*

On December 20, 2001, a wholly-owned subsidiary of the Company entered into a series of credit agreements (the "Credit Agreements") with a bank and entities related to such bank for credit facilities in the aggregate amount of $65,000,000, as amended. The Credit Agreements consisted of term loans aggregating $62,500,000, of which $10,000,000 was denominated in Japanese Yen, and a $2,500,000 multicurrency revolving line of credit, as amended. The proceeds of these term loans were used to finance a portion of the cash used to acquire the Unipath business (Note 4(c)). The per annum interest rate on the loans was the LIBOR plus a spread from 1.50% to 3.50% (and an additional 2.00% in case of default), depending on the type of loan (senior or junior) and the interest period. In addition, interest at 4.00% per annum was capitalized on the junior loan. As part of the Credit Agreements, the Company issued the bank a warrant to acquire 65,000 shares of the Company's common stock at nominal cost. The Company had allocated $1,105,000 of the loan proceeds to this warrant as original issue discount, which represented the fair value of the warrant at the date of issuance. Interest expense, including amortization of original issue discount and deferred financing costs, in 2002 and 2001 was $2,733,110 and $134,233, respectively.

On November 14, 2002, the Company prepaid the outstanding principal balances and any unpaid interest on the term loans and line of credit under the Credit Agreements with proceeds from the senior credit facilities (Note 6(a)). The Company accounted for the prepayment as an early extinguishment of debt. Accordingly, as of November 14, 2002, the remaining unamortized original issue discount and deferred financing costs of $972,380 and $2,237,220, respectively, were recorded as a component of the extraordinary item in the accompanying statements of operations.

*(g) Subordinated Bridge Notes*

The Company entered into a note and warrant purchase agreement pursuant to which, on December 20, 2001, it issued subordinated promissory notes ("Subordinated Bridge Notes") having an aggregate principal amount of $20,000,000 for the purpose of funding its acquisition of the Unipath business (Note 4(c)). The original maturity date of the Subordinated Notes was April 1, 2002, with an

**(6) Long-term Debt (Continued)**

extension option, and interest accrued at 12% per annum, or 18% if and when the maturity date was extended. The Subordinated Bridge Notes were convertible into shares of the Company's Series A Preferred Stock at the option of the holder. Due to such conversion feature of the notes, the Company recorded a discount on the notes in the form of a beneficial conversion feature of $3,242,744 in accordance with EITF Issue No. 98-5, *Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Ratios*, and EITF Issue No. 00-27, *Application of EITF Issue No. 98-5 to Certain Convertible Instruments*. The value assigned to the beneficial conversion feature was being amortized to interest expense over the life of the Subordinated Bridge Notes.

As part of the note and warrant purchase agreement, in addition to the Subordinated Bridge Notes, the Company also issued 10-year warrants to purchase a total of 55,189 shares of the Company's common stock at an exercise price of $18.12 per share. The Company allocated $672,251 of the aggregate proceeds from the Subordinated Bridge Notes to the warrants as original issue discount, which represented the relative fair value of the warrants at the date of issuance, and was amortizing this discount to interest expense over the life of the Subordinated Bridge Notes. Interest expense in 2002 and 2001, including amortization of original issue discount, beneficial conversion feature and deferred financing costs was $2,973,873 and $563,596, respectively.

On March 6, 2002, the Company prepaid the Subordinated Bridge Notes, which had an aggregate outstanding balance of $20,000,000, and related accrued interest of $568,383 using the proceeds from the issuance of series Series A Preferred Stock (Note 12(b)). The Company accounted for the prepayment of the Subordinated Bridge Notes and the reacquisition of the related beneficial conversion feature as an early extinguishment of debt and recorded an extraordinary gain, net of the acceleration of the unamortized original issue discount, initial beneficial conversion feature and deferred financing costs, of $8,339,589. In accordance with EITF Issue Nos. 98-5 and 00-27, the extraordinary gain was calculated by first allocating the reacquisition price to the beneficial conversion feature, measured based on its intrinsic value at the date of extinguishment, with the residual amount allocated to the Subordinated Bridge Notes.

An entity controlled by the Company's chief executive officer was a holder of a $10,000,000 Subordinated Bridge Note and holds a warrant, issued in connection with such note, to purchase 27,594 shares of the Company's common stock.

*(h) Maturities of Long-Term Debt*

The following is a summary of the maturities of long-term debt outstanding on December 31, 2002:

| | |
|---|---|
| 2003 | $ 17,200,390 |
| 2004 | 5,742,003 |
| 2005 | 34,835,000 |
| 2006 | 10,000,002 |
| 2007 | 100,000 |
| Thereafter | 35,000,000 |
| | 102,877,395 |
| Less: Unamortized original issue discount | (1,143,894) |
| | $101,733,501 |

(7) Capital Leases

In connection with the acquisition of IVC, the Company assumed IVC's capital lease obligations. IVC maintains a capital lease for its warehouse and distribution facility, which expires in July 2008 and is renewable for two successive five year periods. This lease was classified as a capital lease as a result of a sale-leaseback transaction that IVC entered into prior to it being acquired by the Company. The aggregate monthly minimum payments remaining under this capital lease are $3,163,333 as of December 31, 2002. In addition, IVC has various other capital leases for certain machinery and equipment and computer equipment that expire at various dates through fiscal 2005, with remaining aggregate monthly minimum payments of $408,894. The following is a schedule of the future minimum lease payments under the capital leases, together with the present value of such payments as of December 31, 2002:

| | |
|---|---|
| 2003 | $ 864,914 |
| 2004 | 608,824 |
| 2005 | 587,239 |
| 2006 | 585,000 |
| 2007 | 585,000 |
| Thereafter | 341,250 |
| Total future minimum lease payments | 3,572,227 |
| Less: Imputed interest | (692,155) |
| Present value of future minimum lease payments | 2,880,072 |
| Less: Current portion | (641,901) |
| | $2,238,171 |

At December 31, 2002, the capitalized amounts of the building, machinery and equipment and computer equipment under the capital leases were as follows:

| | |
|---|---|
| Machinery, laboratory equipment and tooling | $ 304,781 |
| Buildings | 2,185,791 |
| Computer equipment | 55,666 |
| | 2,546,238 |
| Less: Accumulated amortization | (308,067) |
| | $2,238,171 |

The amortization expense of assets recorded under capital leases is included in depreciation and amortization expense of property, plant and equipment.

(8) Postretirement Benefit Plans

*(a) Employee Savings Plans*

The Company and several of its U.S. based subsidiaries sponsor various 401(k) savings plans, to which eligible domestic employees may voluntarily contribute a portion of their income, subject to statutory limitations. In addition to the participants' own contributions to these 401(k) savings plans, the Company matches such contributions up to a designated level. Prior to the split-off from IMT, the Company's employees, at their option, participated in IMT's 401(k) savings plan which had similar

**(8) Postretirement Benefit Plans (Continued)**

terms to the Company's current plans. The Company's results for all periods presented prior to the split-off from IMT include allocations of IMT's matching contribution related to its 401(k) savings plan, which allocations have been made in accordance with SAB No. 55 (Note 1). Total matching contributions related to employee savings plans were $124,508, $14,947 and $8,832 in 2002, 2001 and 2000, respectively.

*(b) Orgenics Severance Obligations*

Israeli law provides that employers have certain severance obligations to employees in Israel. Orgenics' liability for severance pay pursuant to such law is provided by insurance policies and severance pay funds. Severance expenses were $96,000, $12,000 and $68,000 during 2002, 2001 and 2000, respectively. The balance of unfunded severance liability was approximately $10,000 and $141,000 at December 31, 2002 and 2001, respectively, which the Company had accrued for on those dates.

France has a government-run mandatory pension plan to which contributions are made monthly by both the employee and employer based on the employee's gross monthly salary. Orgenics' liability for its employees in France is fully covered by these contributions. In addition, pursuant to industry employment agreements, a lump-sum severance is payable upon retirement to employees still in the service of Orgenics' French subsidiary at the date of retirement. There were no such obligations outstanding as of December 31, 2002 and 2001.

**(9) Derivative Instrument**

The Company entered into an interest rate swap agreement with one of its lenders, effective February 25, 2002, which protects the Company's long-term debt on which interest is charged at the LIBOR against fluctuation in such rate. Under the interest rate swap agreement, the LIBOR is set at a minimum of 3.36% and a maximum of 5.00%. The Company accounts for this derivative instrument in accordance with SFAS No. 133 and related amendments. During 2002, the Company determined that the hedge of the interest rate swap agreement against its long-term debt was ineffective. Accordingly, the Company recorded a charge of $1,223,146 to mark to market this interest rate swap agreement. The charge was recorded in other income (expense), net, in the accompanying statement of operations in 2002 and the value was included in other liabilities in the accompanying balance sheet as of December 31, 2002.

**(10) Commitments and Contingencies**

*(a) Operating Leases*

The Company has operating lease commitments for certain of its facilities and equipment that expire on various dates through 2021. The following schedule outlines future minimum annual rental payments under these leases at December 31, 2002:

| | |
|---|---|
| 2003 | $ 4,634,430 |
| 2004 | 4,291,388 |
| 2005 | 3,912,492 |
| 2006 | 3,744,987 |
| 2007 | 3,423,492 |
| Thereafter | 35,670,452 |
| | $55,677,241 |

Rent expense relating to these operating leases was approximately $4,311,265, $1,028,865 and $485,642 during 2002, 2001 and 2000, respectively.

The operations of the Unipath business in England are currently housed in a 150,000 square foot manufacturing, research and office facility in Bedford, England. The lease of this facility is between Unilever and a third party landlord and the Unipath business in England continues to use the facility pursuant to an agreement with Unilever in connection with the acquisition. Future minimum annual rent payments under this facility lease range from 1,460,000 British Pounds Sterling to 1,560,000 British Pounds Sterling (approximately $2,350,000 to $2,511,000) with upward adjustments every 5 years, but only to the extent the rent is below market rate. The lease expires in December 2021. Unilever has agreed to use its best efforts to obtain the landlord's consent, which consent is required under the lease agreement and cannot be unreasonably withheld, so it may assign the lease to the Company for its remaining term. Because the Company is required to pay all amounts owed under the lease, as agreed upon at the acquisition, it has included in the table above all future minimum lease payments under this facility lease.

*(b) Capital Expenditure Commitments*

At December 31, 2002, the Unipath business in England had total outstanding non-cancelable equipment purchase commitments of 1,225,906 British Pounds Sterling (approximately $1,973,341). The remaining entities and businesses of the Company did not have material outstanding non-cancelable equipment purchase commitments on that date.

*(c) Legal Proceedings*

Because of the nature of its business, the Company may be subject at any particular time to consumer product claims or various other lawsuits arising in the ordinary course of its business, including employment matters, and expects 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. In addition, the Company aggressively defends its patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties, which can be expensive and result in counterclaims challenging the validity of the Company's patents and other rights.

(10) Commitments and Contingencies (Continued)

In April 2001, 68 consumers brought an action in London, England, claiming defects in the Persona contraceptive device, which is sold by the Unipath business in Europe, as well as negligence and breach of contract, all allegedly leading to unwanted pregnancies by the claimants in or prior to 1998. The case is not expected to be ready for trial by a judge until late 2003 or 2004. The Company believes that it has substantial defenses to the claims and intends to vigorously defend this litigation. The case is insured, in the aggregate, by Unilever's product liability insurance up to 50,000,000 British Pounds Sterling (approximately $80,500,000 at December 31, 2002) or more, depending on when events giving rise to the consumers' suit occurred. As a result, the Company does not believe that an adverse ruling against it would have a material adverse impact on its sales, operations or financial performance.

In April 1998, Abbott Laboratories ("Abbott") commenced a patent infringement lawsuit against IMT and Princeton BioMeditech Corporation ("PBM"). Abbott claims that certain of IMT's pregnancy detection and ovulation prediction products (now the Company's products to the extent they are still sold) infringe patents that Abbott claims to have exclusive rights to in the United States. Abbott is seeking an order finding that IMT and PBM infringe such patents and an order to permanently enjoin IMT and PBM from infringing such patents, reimbursement of certain damages and a recall of all of IMT's existing products found to infringe such patents. IMT and PBM moved for summary judgment on their defense that the Abbott patents are invalid, and in September 2000, the court granted partial summary judgment, holding that certain key claims on Abbott's patents are invalid as a matter of law. The court refused to grant summary judgment on Abbott's claims of infringement or IMT's remaining claims of invalidity of Abbott's patents. Abbott is seeking the court's reconsideration of the partial summary judgment and the court has not ruled on this motion. No trial date has been set at this time. In connection with its split-off from IMT, the Company assumed all obligations and liabilities of IMT arising out of this matter. The Company believes that it has strong defenses against Abbott's claims and it will continue to defend the case vigorously. However, a final ruling of this suit against IMT or the Company could have a material adverse impact on the Company's sales, operations or financial performance.

On January 3, 2000, Becton, Dickinson and Company ("BD") filed suit against Selfcare, Inc., which became IMT, alleging that certain pregnancy and ovulation products sold by IMT (and now by the Company) infringe certain BD patents. In connection with the split-off from IMT, the Company assumed all obligations and liabilities of IMT arising out of this matter. The parties settled this litigation during the third quarter of 2002. In the settlement, neither party admitted any liability and the Company obtained a fully paid-up, royalty-free license from BD for an amount which was not material to it.

*(d) Orgenics Royalty Commitment*

Orgenics has received participation payments in programs sponsored by the Chief Scientist of the Ministry of Industry and Commerce of Israel (the "Chief Scientist") for the support of its research and development projects. In the event that development of the products in which the Chief Scientist participates is successful, Orgenics will be obligated to pay royalties at the rate of 2.0% to 3.5% of the sales of products developed with funds provided by the Chief Scientist, up to an amount equal to 100% of the Chief Scientist's participation payments to such projects. The balance of the maximum contingent royalty as of December 31, 2002 was approximately $200,000. Orgenics does not have any liability to the State of Israel for amounts received in support of unsuccessful programs or unsaleable products. During 2001 and 2000, Orgenics paid approximately $169,000 and $206,000, respectively, in royalties to the Chief Scientist. There were no royalties paid during 2002.

## (11) Earnings Per Share

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

| | 2002 | 2001 | 2000 |
|---|---|---|---|
| *Numerator:* | | | |
| (Loss) income from continuing operations | $(24,116,785) | $(24,462,202) | $2,779,605 |
| Dividends, interest and amortization of beneficial conversion feature related to Series A Preferred Stock (Note 12(b)) | (11,948,457) | — | — |
| (Loss) income from continuing operations available to common stockholders | (36,065,242) | (24,462,202) | 2,779,605 |
| Income (loss) from discontinued operations | — | 57,895 | (597,784) |
| (Loss) income before extraordinary items and accounting change available to common stockholders | (36,065,242) | (24,404,307) | 2,181,821 |
| Extraordinary items | 5,129,989 | (326,580) | — |
| Cumulative effect of a change in accounting principle | (12,148,205) | — | — |
| Net (loss) income available to common stockholders | $(43,083,458) | $(24,730,887) | $2,181,821 |
| *Denominator:* | | | |
| Weighted average shares (Note 2(k)) | 9,939,664 | 6,367,657 | 4,726,390 |
| *(Loss) income per share—basic and diluted:* | | | |
| (Loss) income from continuing operations | $ (3.63) | $ (3.84) | $ 0.59 |
| Income (loss) from discontinued operations | — | 0.01 | (0.13) |
| (Loss) income before extraordinary items and accounting change | (3.63) | (3.83) | 0.46 |
| Extraordinary items | 0.52 | (0.05) | — |
| Cumulative effect of a change in accounting principle | (1.22) | — | — |
| Net (loss) income | $ (4.33) | $ (3.88) | $ 0.46 |

The Company had the following potential dilutive securities outstanding on December 31, 2002: (a) options and warrants to purchase an aggregate of 3,553,280 shares of the Company's common stock at a weighted average exercise price of $14.65 per share, (b) Series A Preferred Stock convertible into an aggregate of 646,120 shares of the Company's common stock, (c) 3% Convertible Notes convertible into an aggregate of 343,840 shares of the Company's common stock, (d) 1,214,419 shares of unvested restricted common stock issued to certain executive officers, and (e) 15,902 shares of common stock held in escrow.

The Company had the following potential dilutive securities outstanding on December 31, 2001: (a) options and warrants to purchase an aggregate of 2,575,807 shares of the Company's common stock at a weighted average exercise price of $12.85 per share, (b) Series A Preferred Stock convertible into

**(11) Earnings Per Share (Continued)**

an aggregate of 3,990,000 shares of the Company's common stock, (c) 1,817,572 shares of unvested restricted common stock issued to certain executive officers, and (d) 31,804 shares of common stock held in escrow.

Potential dilutive securities were not included in the computation of diluted loss per share in 2002 and 2001 because the inclusion thereof would be antidilutive. There were no dilutive securities outstanding during 2000.

**(12) Stockholders' Equity**

In this Note, all amounts pertaining to shares and share prices for all securities issued or granted prior to the Company's split-off from IMT in November 2001 have been restated assuming the stock split described in Note 1, as if the split-off from IMT had occurred on the dates such securities were issued.

*(a) Common Stock*

As of December 31, 2002, the Company had 50,000,000 shares of common stock, $0.001 par value, authorized, of which 14,907,191 shares were issued and outstanding, 646,120 shares were reserved for issuance upon conversion of outstanding Series A Preferred Stock, 343,840 shares were reserved for issuance upon conversion of outstanding 3% Convertible Notes, 3,581,932 shares were reserved for issuance upon grant and exercise of stock options under current stock option plans and 799,627 shares were reserved for issuance upon exercise of outstanding warrants.

*(b) Preferred Stock*

As of December 31, 2002, the Company had 5,000,000 shares of preferred stock, $0.001 par value, authorized, of which 2,666,667 shares were designated as Series A Preferred Stock, $0.001 par value. On March 6, 2002, the Company sold to private investors 531,913 shares of Series A Preferred Stock at $39.01 per share for gross proceeds of $20,749,990 for purposes of prepaying the Subordinated Bridge Notes (Note 6(g)). On December 20, 2001, the Company sold to private investors 1,995,000 shares of Series A Preferred Stock at $30.00 per share for gross proceeds of $59,850,000 to help finance its acquisition of the Unipath business (Note 4(c)). The private investors of the December 2001 issuance include certain directors of the Company and entities affiliated with such directors and the Company's chief executive officer, who in the aggregate purchased 626,666 shares of Series A Preferred Stock. The number of shares of common stock to be issued upon any voluntary conversion of one share of Series A Preferred Stock is equal to such number as is determined by dividing $30.00 by the conversion price in effect at the time of conversion. As of December 31, 2002, the conversion price was $15.00, subject to adjustment. Accordingly, each share of Series A Preferred Stock was convertible into two shares of common stock at December 31, 2002. Starting on the second anniversary of the original issue date, the Company may convert any remaining Series A Preferred Stock into common stock in the event that the average closing price of its common stock exceeds $20 for any consecutive 30 trading day period. During 2002, 2,203,853 shares of Series A Preferred Stock were converted into 4,407,706 shares of the Company's common stock and 323,060 shares of Series A Preferred Stock remained outstanding as of December 31, 2002. There were no conversions during 2001.

Each share of Series A Preferred Stock accrues dividends on a quarterly basis at $2.10 per annum, but only on those trading days when the closing price of the Company's common stock is less than

(12) Stockholders' Equity (Continued)

$15.00. As a result, the Company accrued dividends of $325,725 during 2002, which reduced earnings available to common stockholders in the computation of earnings per share (Note 11). No dividends were recorded in 2001, as the Company's stock price did not close below $15.00 during the period in 2001, in which Series A Preferred Stock were outstanding. Dividends accrued are payable only if declared by the board of directors and therefore, upon voluntary conversion, any undeclared dividends on the converted shares of Series A Preferred Stock are forfeited. Until the second anniversary of the original issue date, accrued dividends, if any, must be paid in the Company's common stock (using the same conversion ratio as described above in connection with a voluntary conversion of Series A Preferred Stock). Thereafter, the Company has the option to pay dividends in cash or common stock. In addition, the Company's senior credit agreement currently prohibits it from paying dividends (Note 6(a)).

The effective purchase price for the shares of common stock underlying the Series A Preferred Stock issued on March 6, 2002 and December 20, 2001 represented a discount of $2.70 (or 12%) and $2 (or 11.8%), respectively, to the fair value of the Company's common stock on the issuance date. In accordance with EITF Issue No. 98-5 and EITF Issue No. 00-27, the Company recorded a beneficial conversion feature in the form of a discount on the Series A Preferred Stock of $2,867,011 and $7,980,000, respectively, which is being amortized to accumulated deficit over the redemption period (as discussed below). The amortization of this discount reduces earnings available to common stockholders in the computation of earnings per share. In 2002, the Company amortized $9,574,807 of such discount, of which $8,811,624 represented acceleration of amortization due to conversions of Series A Preferred Stock. The total amount of the discount amortized in 2001 was not material to the Company's consolidated financial statements.

Because the Series A Preferred Stock may be redeemed upon a vote by the holders of at least 66⅔% of the outstanding shares on or after June 30, 2011, the Company has classified the outstanding Series A Preferred Stock outside of stockholders' equity in the accompanying consolidated balance sheets and statements of stockholders equity as of December 31, 2002 and 2001. The redemption price per share of Series A Preferred Stock will be equal to $30.00 plus accrued interest calculated at 5% per annum from the date of issuance. The Company recorded accrued interest of $2,047,925 in 2002, which reduced earnings available to common stockholders in the computation of earnings per share. The amount of the accrued interest in 2001 was not material to the Company's consolidated financial statements.

The holders of Series A Preferred Stock have liquidation preferences over the holders of the Company's common stock and other classes of stock, if any, outstanding at the time of liquidation. Upon liquidation, the holders of outstanding Series A Preferred Stock would receive an amount equal to $30 per share of Series A Preferred Stock plus any undeclared or unpaid dividends. As of December 31, 2002, the liquidation value of the outstanding Series A Preferred Stock was $9,900,836.

Each holder of Series A Preferred Stock currently has two votes for every one share of Series A Preferred Stock, which is equal to the number of common shares, if converted. The holders of Series A Preferred Stock shall vote together with the holders of the Company's common stock as a single class.

*(c) Stock Options and Awards*

In 2001, the Company adopted the 2001 Stock Option and Incentive Plan (the "2001 Plan") which allows for the issuance of up to 4,824,081 shares of common stock and other awards. The 2001 Plan is

**(12) Stockholders' Equity (Continued)**

administered by the Compensation Committee of the Board of Directors in order to select the individuals eligible to receive awards, determine or modify the terms and conditions of the awards granted, accelerate the vesting schedule of any award and generally administer and interpret the 2001 Plan. The key terms of the 2001 Plan permit the granting of incentive or nonqualified stock options with a term of up to ten years and the granting of stock appreciation rights, restricted stock awards, unrestricted stock awards, performance share awards and dividend equivalent rights. The 2001 Plan also provides for option grants to nonemployee directors and automatic vesting acceleration of all options and stock appreciation rights upon a change in control, as defined by the 2001 Plan.

On August 15, 2001, the Company sold to its chief executive officer 1,168,191 shares of restricted common stock at a price of $9.13 per share. Two-thirds of the restricted stock, or 778,794 shares, vest ratably over 36 months; the remaining one-third, or 389,397 shares, vests ratably over 48 months. Except for the par value of the common stock, which was paid in cash, the chief executive officer purchased the restricted stock with a five-year promissory note, which, for accounting purposes, was treated as a non-recourse note. The balance of the promissory note is recorded as a note receivable and is classified in stockholders' equity in the accompanying consolidated balance sheets. The note bears interest at an annual rate of 4.99%. Interest income recorded under this note amounted to $532,212 and $199,580 in 2002 and 2001, respectively. The Company accounted for this arrangement pursuant to FIN No. 44, EITF Issue No. 95-16, *Accounting for Stock Compensation Arrangements with Employer Loan Features under APB Opinion No. 25*, and EITF Issue No. 00-23, *Issues Related to Accounting for Stock Compensation under APB Opinion No. 25 and FASB Interpretation No. 44*. Accordingly, on November 20, 2001, the date on which this arrangement was approved by the stockholders, the Company measured total compensation expense to be approximately $10,595,492 based on the intrinsic value of the stock on that date. The amount of compensation expense is deferred and amortized ratably over the vesting periods of the restricted stock because, under the terms of the original restricted stock agreement, the Company could repurchase unvested shares at cost in certain circumstances. In February 2002, the terms of the restricted stock agreement were amended, pursuant to which the Company may repurchase unvested shares at the then fair value in certain circumstances. Also, in connection with this amendment, the chief executive officer surrendered 50,000 shares of his nonqualified stock options in the Company. Because the repurchase rights on unvested shares are now at fair value, the Company fully amortized the remaining portion of the deferred compensation expense associated with the restricted stock in 2002. Amortization of deferred compensation related to this restricted stock arrangement was $10,144,937 and $450,555 in 2002 and 2001, respectively, which was recorded as stock-based compensation in the accompanying consolidated statements of operations.

In August 2001, the Company granted two nonqualified stock options to purchase an aggregate of 778,794 shares of common stock at an exercise price of $6.20 per share to two other key executive officers. These options were set to expire on January 31, 2002. In December 2001, the executive officers exercised these options (one fully; one partially) by paying cash in the amount of par value and delivering promissory notes for the difference, as permitted pursuant to the terms of the original grant. For accounting purposes, the promissory notes were treated as non-recourse notes. The balance of the promissory notes is recorded as a note receivable and classified in stockholders' equity in the accompanying consolidated balance sheets. The notes bear interest at an annual rate of 3.97%, the applicable federal rate for a five-year note in effect during the month of exercise. Interest income recorded under these notes amounted to $159,813 and $12,029 in 2002 and 2001, respectively. Shares issued upon exercise vest ratably over 36 months. Under certain circumstances, the Company may

(12) Stockholders' Equity (Continued)

repurchase unvested shares at the then fair value. One of these executive officers exercised part of the option for only a portion of the underlying shares; as a result, in accordance with the terms of the original option agreement, the Company granted a replacement option to this executive officer for the remaining unexercised shares with an exercise price equal to the fair value of the common stock on the date of grant. The Company accounted for these arrangements under FIN No. 44, EITF Issue Nos. 95-16 and 00-23. Accordingly, on November 20, 2001, the date on which these arrangements were approved by the stockholders, the Company measured total compensation expense to be $9,345,528 based on the intrinsic value of the stock on that date. Because the repurchase rights on unvested shares are at fair value, the Company recorded the full intrinsic value as stock-based compensation in the accompanying consolidated statements of operations in 2001.

The Company also granted immediately after the effective date of the split-off from IMT options to purchase an additional 389,397 shares of common stock to these two key executive officers. These options vest ratably over four years and expire 10 years from the date of grant. The exercise price per share was equal to the fair value of the Company's common stock on the date of grant. The options permit exercise for cash, the Company's shares paid for at least 6 months prior to the exercise date or with proceeds from a promissory note that will contain terms that are substantially the same as those described above.

In connection with the Credit Agreements (Note 6(f)), the Company's chief executive officer was required to enter into a lock up agreement with the bank, pursuant to which he was restricted in the trading of the Company's securities for various specified periods and amounts. The lock up agreement has since been terminated as a result of the prepayments of outstanding borrowings under the Credit Agreement. In consideration of his entry into this lock up agreement, the Company granted the chief executive officer an option to acquire 115,000 shares of the Company's common stock at $17.15 per share (the fair value of the Company's common stock on the date of grant). Simultaneously, an entity controlled by the Company's chief executive officer also received a warrant to purchase 385,000 shares of the Company's common stock.

Upon the split-off and merger in November 2001, each outstanding IMT stock option (the "IMT Options") was exchanged for an option to purchase shares of the Company's common stock (the "Company Options") at an exchange ratio of 0.20 and an option to purchase shares of Johnson & Johnson common stock at an exchange ratio of 0.5395. The new exercise prices of the Company Options and the Johnson and Johnson options were determined based on the relative fair values of the Johnson & Johnson common stock and the Company's common stock on the first trading day immediately after the split-off and merger, taking into consideration the relative exchange ratios. The per share numbers and exercise prices of stock options granted prior to the split-off and merger date in the following tables have been restated to reflect the exchange of the IMT Options for the Company Options, as if each exchange occurred on the grant date of the applicable IMT Option.

**(12) Stockholders' Equity (Continued)**

The following summarizes all stock option activity during each of the years ended December 31:

| | 2002 | | 2001 | | 2000 | |
|---|---|---|---|---|---|---|
| | Options | Weighted Average Exercise Price | Options | Weighted Average Exercise Price | Options | Weighted Average Exercise Price |
| Outstanding at January 1 | 1,954,927 | $12.77 | 886,153 | $ 2.06 | 1,048,433 | $1.93 |
| Granted | 1,116,164 | 17.72 | 2,335,347 | 12.68 | 46,335 | 4.34 |
| Exercised | (140,495) | 4.97 | (1,120,857) | 12.04 | (155,669) | 1.49 |
| Terminated | (176,943) | 17.95 | (145,716) | 6.55 | (52,946) | 2.88 |
| Outstanding at December 31 | 2,753,653 | $14.84 | 1,954,927 | $12.77 | 886,153 | $2.06 |
| Exercisable at December 31 | 1,134,194 | $12.25 | 775,229 | $ 7.55 | 747,874 | $1.94 |

The following represents additional information related to stock options outstanding and exercisable at December 31, 2002:

| | Outstanding | | | Exercisable | |
|---|---|---|---|---|---|
| Exercise Price | Number of Shares | Weighted Average Remaining Contract Life | Weighted Average Exercise Price | Number of Shares | Weighted Average Exercise Price |
| $0.75 | 20,401 | 1.81 | $ 0.75 | 20,401 | $ 0.75 |
| 1.24 - 1.80 | 164,646 | 4.36 | 1.46 | 164,646 | 1.46 |
| 1.88 - 2.68 | 131,191 | 6.44 | 2.42 | 131,191 | 2.42 |
| 2.89 - 4.32 | 14,414 | 5.23 | 3.96 | 14,414 | 3.96 |
| 4.38 - 6.48 | 78,599 | 2.47 | 5.48 | 78,599 | 5.48 |
| 6.67 - 9.60 | 151,477 | 9.40 | 9.32 | 18,477 | 7.55 |
| 10.85 - 16.17 | 1,188,601 | 9.03 | 14.82 | 449,414 | 15.19 |
| 16.32 - 24.14 | 961,607 | 8.08 | 19.47 | 229,335 | 18.37 |
| 25.40 - 35.47 | 21,540 | 7.87 | 28.07 | 6,540 | 30.21 |
| 41.05 - 59.58 | 10,938 | 6.52 | 44.83 | 10,938 | 44.83 |
| 62.42 - 75.18 | 5,334 | 6.01 | 65.42 | 5,334 | 65.42 |
| 102.13 - 141.85 | 4,341 | 3.75 | 120.76 | 4,341 | 120.76 |
| 165.96 | 564 | 4.91 | 165.96 | 564 | 165.96 |
| | 2,753,653 | 8.02 | $ 14.84 | 1,134,194 | $ 12.25 |

*(d) Warrants*

Upon the split-off from IMT in November 2001, each outstanding IMT warrant (the "IMT Warrants") was exchanged for a warrant to purchase shares of the Company's common stock (the "Company Warrants") at an exchange ratio of 0.20 and a warrant to purchase shares of Johnson and Johnson common stock at an exchange ratio of 0.5935. The new exercise prices of the Company Warrants and the Johnson and Johnson warrants were determined based on the relative fair values of the Johnson & Johnson common stock and the Company's common stock on the first trading day immediately after the split-off and merger, taking into consideration the relative exchange ratios. The

(12) Stockholders' Equity (Continued)

per share numbers and exercise prices of warrants issued prior to the split-off and merger date in the following tables have been restated to reflect the exchange of the IMT Warrants for the Company Warrants, as if each exchange occurred on the issuance date of the applicable IMT Warrant.

The following is a summary of all warrant activity during the three years ended December 31, 2002:

| | Number of Shares | Exercise Price | Weighted Average Exercise Price |
|---|---|---|---|
| Warrants outstanding and exercisable, December 31, 1999 | 147,336 | $ 0.75 - 6.80 | $ 3.49 |
| Granted | 23,687 | 3.81 - 7.55 | 5.25 |
| Exercised | (22,553) | 3.02 - 6.80 | 6.52 |
| Cancelled | (8,236) | 4.93 - 6.80 | 5.52 |
| Warrants outstanding and exercisable, December 31, 2000 | 140,234 | 0.75 - 7.55 | 3.18 |
| Granted | 524,564 | 0.001 - 21.28 | 15.06 |
| Exercised | (43,918) | 3.02 - 7.55 | 5.06 |
| Warrants outstanding and exercisable, December 31, 2001 | 620,880 | 0.75 - 21.28 | 13.09 |
| Granted | 237,700 | 10.90 - 13.54 | 13.10 |
| Exercised | (58,918) | 0.75 - 7.50 | 0.94 |
| Cancelled | (35) | 6.23 | 6.23 |
| Warrants outstanding and exercisable, December 31, 2002 | 799,627 | $0.001 - 21.28 | $13.98 |

The following represents additional information related to warrants outstanding and exercisable at December 31, 2002:

| | Outstanding and Exercisable | | |
|---|---|---|---|
| Exercise Price | Number of Shares | Weighted Average Remaining Contract Life | Weighted Average Exercise Price |
| $0.001 | 65,000 | 8.97 | $0.001 |
| 3.02 - 4.52 | 18,687 | 2.06 | 3.66 |
| 4.54 - 6.27 | 16,590 | 5.45 | 5.08 |
| 7.37 - 10.90 | 42,086 | 9.78 | 10.73 |
| 11.55 - 17.15 | 597,414 | 5.83 | 15.87 |
| 18.12 - 21.28 | 59,850 | 8.35 | 18.37 |
| | 799,627 | 6.38 | $13.98 |

The majority of the warrants included in the table above were issued in connection with debt and equity financings, or amendments thereto, of which warrants to purchase an aggregate of 428,526 shares of the Company's common stock were issued to officers and directors of the Company or

**(12) Stockholders' Equity (Continued)**

entities controlled by these officers and directors and were outstanding at December 31, 2002. The value of warrants issued in connection with debt financings have yielded original issue discounts and additional interest expense of $491,694 in 2002 and $102,567 for the period from the split-off and merger date through December 31, 2001. The Company believes that its equity classification is appropriate for all outstanding warrants, pursuant to the provisions of EITF Issue No. 00-19, *Determination of Whether Share Settlement Is within the Control of the Issuer for Purposes of Applying EITF Issue No. 96-13, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock.*

*(e) Employee Stock Purchase Plan*

In 2001, the Company adopted the 2001 Employee Stock Purchase Plan under which eligible employees will be allowed to purchase shares of the Company's common stock at a discount through periodic payroll deductions. Purchases may occur at the end of every six month offering period at a purchase price equal to 85% of the market value of the Company's common stock at either the beginning or end of the offering period, whichever is lower. The Company may issue up to 500,000 shares of common stock under this plan. At December 31, 2002, 18,356 shares had been issued under this plan.

*(f) Executive Bonus Plan*

In 2001, the Company adopted a stockholder approved executive bonus plan (the "Executive Bonus Plan") which was amended in February 2002. Pursuant to the Executive Bonus Plan, as amended, certain key executives of the Company are entitled to receive, on an annual basis, option grants to be awarded at fair value on date of grants if shares of the Company's common stock attain certain targeted prices per share. Performance determinations are to be made at the end of each calendar year, starting with December 31, 2002 and ending with December 31, 2005. The maximum number of shares for which options may be granted under the Executive Bonus Plan, as amended, is 712,600. No performance targets have been achieved as of December 31, 2002.

**(13) Income Taxes**

The Company's income tax provision in 2002 mainly represents those recorded by its foreign subsidiaries Unipath Limited in England and Inverness Medical Switzerland GmbH in Switzerland and its U.S. subsidiary, Wampole. In 2001 and 2000, the income tax provisions represent mainly those recorded by Inverness Medical, Inc. ("IMI"). (Loss) or income from continuing operations before income taxes consists of the following:

| | 2002 | 2001 | 2000 |
|---|---|---|---|
| United States | $(31,743,853) | $(13,359,363) | $3,250,590 |
| Foreign | 10,310,360 | (8,968,480) | 1,310,259 |
| | $(21,433,493) | $(22,327,843) | $4,560,849 |

For federal and some state income tax filing purposes, the results of IMI's operations are consolidated with IMT's through the date of the split-off and merger (November 21, 2001). IMI has stand-alone tax filing responsibilities in some states. Prior to the split-off from IMT, the tax accounts

(13) Income Taxes (Continued)

maintained by IMI and the Company's other subsidiaries have been computed using the separate return method. IMT had been in a net loss position and, accordingly, paid virtually no income taxes in any jurisdiction. Prior to the split-off from IMT, IMI had a tax sharing agreement with IMT, under which IMT agreed to pay all of IMI's tax liabilities (or offset these liabilities via IMT's net operating loss carryforwards) until IMI's cumulative taxable income (beginning January 1, 1998) exceeded $15,500,000. Once IMI's cumulative taxable income passed this threshold, IMI was required to pay a dividend to IMT equal to 40% of the amount that exceeds the threshold. During 2000, IMI surpassed the threshold and IMI has accrued a dividend to IMT of $1,187,000 in 2000. Pursuant to this agreement, IMI recorded a capital contribution from IMT for taxes paid by IMT or offset via IMT's net operating loss carryforward. Upon the split-off from IMT, this agreement was cancelled.

The Company's primary temporary differences that give rise to the deferred tax asset and liability are nondeductible reserves and accruals and differences in bases of the tangible and intangible assets. The income tax effects of these temporary differences are as follows:

| | December 31, | |
|---|---|---|
| | 2002 | 2001 |
| Deferred tax assets: | | |
| Net operating loss (NOL) carryforwards | $12,260,828 | $ 4,741,851 |
| Nondeductible reserves | 4,917,543 | 1,564,403 |
| Nondeductible accruals | 6,584,132 | 1,803,519 |
| Nondeductible stock-based compensation | 191,693 | 4,169,910 |
| Nondeductible write-off of tangible assets | 9,517,413 | 1,466,786 |
| Difference between book and tax bases of tangible assets | 1,159,839 | — |
| Valuation allowance | (28,196,984) | (12,279,683) |
| Deferred tax asset | $ 6,434,464 | $ 1,466,786 |
| Deferred tax liabilities: | | |
| Difference between book and tax bases of tangible assets | $ 4,110,362 | $ 2,044,019 |
| Difference between book and tax bases of intangible assets | 5,254,652 | — |
| Deferred tax liability | $ 9,365,014 | $ 2,044,019 |

As of December 31, 2002, the Company had approximately $21,119,000 and $19,059,000 of domestic and foreign net operating loss carryforwards, respectively, which either expire on various dates through 2022 or can be carried forward indefinitely. These loss carryforwards are available to reduce future federal and foreign taxable income, if any. These loss carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. The valuation allowance relates to the Company's U.S. net operating losses and deferred tax assets and certain other foreign deferred tax assets and is recorded based upon the uncertainty surrounding their realizability, as these assets can only be realized via profitable operations in the respective tax jurisdictions.

No amount for U.S. income tax has been provided on undistributed earnings of the Company's foreign subsidiaries because the Company considers such earnings to be indefinitely reinvested. In the

**(13) Income Taxes (Continued)**

event of distribution of those earnings in the form of dividends or otherwise, the Company would be subject to both U.S. income taxes, subject to an adjustment for foreign tax credits, and foreign withholding taxes payable to certain foreign tax authorities. Determination of the amount of U.S. income tax liability that would be incurred is not practicable because of the complexities associated with its hypothetical calculation; however, unrecognized foreign tax credit carryforwards may be available to reduce some portion of the U.S. tax liability.

The following table presents the components of the Company's provision for income taxes:

| | 2002 | 2001 | 2000 |
|---|---|---|---|
| Current— | | | |
| Federal | $ — | $1,061,695 | $1,399,050 |
| State | 322,003 | 620,642 | 431,946 |
| Foreign | 2,356,914 | 33,207 | 18,000 |
| | 2,678,917 | 1,715,544 | 1,848,996 |
| Deferred— | | | |
| Federal | — | 320,013 | (51,763) |
| State | — | 98,802 | (15,989) |
| Foreign | 4,375 | — | — |
| | 4,375 | 418,815 | (67,752) |
| Total tax provision | $2,683,292 | $2,134,359 | $1,781,244 |

The following table presents a reconciliation from the U.S. statutory tax rate to the Company's effective tax rate from continuing operations:

| | 2002 | 2001 | 2000 |
|---|---|---|---|
| Statutory rate | (34)% | (34)% | 34% |
| Effect of losses and expenses not benefited | 20 | 5 | 17 |
| Rate differential on foreign earnings | (8) | 2 | (4) |
| State income taxes, net of federal benefit | 2 | 2 | 6 |
| Change in valuation allowance | 33 | 34 | (14) |
| | 13% | 9% | 39% |

**(14) Financial Information by Segment**

Under SFAS No. 131, *Disclosures about Segments of an Enterprise and Related Information*, operating segments are defined as components of an enterprise about which separate financial information is available that is evaluated regularly by the chief operating decision maker, or decision making group, in deciding how to allocate resources and in assessing performance. The Company's chief operating decision making group is composed of the chief executive officer and members of senior management. The Company's reportable operating segments are Consumer Products (comprised of consumer diagnostic products and vitamins and nutritional supplements), Professional Diagnostic Products, and Corporate and Other.

(14) Financial Information by Segment (Continued)

The accounting policies of the segments are the same as those described in the summary of significant accounting policies. The Company evaluates performance based on EBITDA. Revenues are attributed to geographic areas based on where the customer is located. Segment information for 2002, 2001, and 2000 are as follows:

| 2002 | Consumer Products | Professional Diagnostic Products | Corporate and Other | Total |
|---|---|---|---|---|
| Net revenue to external customers | $173,592,539 | $ 34,304,857 | $ — | $207,897,396 |
| EBITDA | 22,271,083 | 6,194,848 | (5,468,174) | 22,997,757 |
| Depreciation and amortization | 7,770,625 | 2,090,515 | 446,572 | 10,307,712 |
| Charge related to asset impairment | 12,681,581 | — | — | 12,681,581 |
| Stock-based compensation | — | — | 10,624,893 | 10,624,893 |
| Interest income | 286,678 | 29,050 | 1,107,447 | 1,423,175 |
| Interest expense | 3,260,408 | 1,204,854 | 4,911,109 | 9,376,371 |
| Fair value on interest rate swap | — | — | 1,223,146 | 1,223,146 |
| Provision for income taxes | 2,023,791 | 823,581 | (164,080) | 2,683,292 |
| Extraordinary gain from early extinguishment of debt | — | — | 5,129,989 | 5,129,989 |
| Assets | 220,713,506 | 107,698,387 | 29,333,781 | 357,745,674 |
| Expenditures for property, plant and equipment | 4,420,301 | 1,474,555 | 182,284 | 6,077,140 |

**(14) Financial Information by Segment (Continued)**

| 2001 | Consumer Products | Professional Diagnostic Products | Corporate and Other | Total |
|---|---|---|---|---|
| Net revenue to external customers | $ 36,676,900 | $10,590,774 | $ — | $ 47,267,674 |
| EBITDA | 5,626,102 | (1,464,345) | (3,860,711) | 301,046 |
| Depreciation and amortization | 2,083,301 | 430,998 | 726,462 | 3,240,761 |
| Charge for in-process research and development | 6,980,221 | — | — | 6,980,221 |
| Stock-based compensation | — | — | 10,440,588 | 10,440,588 |
| Interest income | 89,030 | — | 296,099 | 385,129 |
| Interest expense— | | | | |
| External | 790,196 | 205,223 | 703,443 | 1,698,862 |
| To IMT | 115,397 | — | 153,060 | 268,457 |
| Total interest expense | 905,593 | 205,223 | 856,503 | 1,967,319 |
| Provision for income taxes | 1,966,359 | 18,000 | 150,000 | 2,134,359 |
| Income from discontinued operations | — | — | 57,895 | 57,895 |
| Extraordinary loss from early extinguishment of debt | 326,580 | — | — | 326,580 |
| Assets | 194,322,644 | 42,023,783 | 42,174,717 | 278,521,144 |
| Expenditures for property, plant and equipment | 2,371,986 | 394,000 | 827,729 | 3,593,715 |

| 2000 | Consumer Products | Professional Diagnostic Products | Corporate and Other | Total |
|---|---|---|---|---|
| Net revenue to external customers | $ 39,022,407 | $10,681,000 | $ 24,140 | $ 49,727,547 |
| EBITDA | 9,346,572 | 1,239,000 | (1,255,262) | 9,330,310 |
| Depreciation and amortization | 1,956,597 | 398,000 | 379,392 | 2,733,989 |
| Interest income | 12,442 | 15,000 | — | 27,442 |
| Interest expense— | | | | |
| External | 1,475,451 | 265,000 | — | 1,740,451 |
| To IMT | 130,356 | — | 164,665 | 295,021 |
| Total interest expense | 1,605,807 | 265,000 | 164,665 | 2,035,472 |
| Provision for income taxes | 1,763,244 | 18,000 | — | 1,781,244 |
| Loss from discontinued operations | — | — | 597,784 | 597,784 |
| Assets from continuing operations | 46,239,592 | 6,423,591 | 3,949,425 | 56,612,608 |
| Expenditures for property, plant and equipment | 457,277 | 329,000 | 77,514 | 863,791 |

(14) *Financial Information by Segment (Continued)*

| | 2002 | 2001 | 2000 |
|---|---|---|---|
| Reconciliation of EBITDA to (Loss) Income from Continuing Operations | | | |
| EBITDA | $ 22,997,757 | $ 301,046 | $ 9,330,310 |
| Depreciation and amortization expense | (10,307,712) | (3,240,761) | (2,733,989) |
| Interest expense | (9,376,371) | (1,967,319) | (2,035,472) |
| Income taxes | (2,683,292) | (2,134,359) | (1,781,244) |
| Legal settlement | (217,547) | — | — |
| Other noncash items: | (24,529,620) | (17,420,809) | — |
| (Loss) income from continuing operations | $(24,116,785) | $(24,462,202) | $ 2,779,605 |

| | 2002 | 2001 | 2000 |
|---|---|---|---|
| Revenue by Geographic Area | | | |
| United States | $119,654,442 | $ 33,498,186 | $37,496,143 |
| Europe | 69,224,342 | 6,342,151 | 4,417,330 |
| Other | 19,018,612 | 7,427,337 | 7,814,074 |
| | $207,897,396 | $ 47,267,674 | $49,727,547 |

| | December 31, | |
|---|---|---|
| | 2002 | 2001 |
| Long-lived Tangible Assets by Geographic Area | | |
| United States | $23,042,865 | $ 1,609,574 |
| United Kingdom | 18,333,154 | 14,993,888 |
| Ireland | 3,193,838 | 2,559,877 |
| Other | 1,230,232 | 1,362,889 |
| | $45,800,089 | $20,526,228 |

(15) Transactions with Inverness Medical Technology, Inc. and Affiliates

*(a) Management services*

For the periods prior to the split-off from IMT, the results of the Company's subsidiary, IMI, include expenses that represent cross-charges to it by IMT. Such cross-charges include, among other things, support services such as financial, computer, legal, sales, marketing, customer support and accounting, as well as rent and administrative costs. IMI recorded cross-charges from IMT of approximately $3,033,475 and $2,733,061 during 2001 and 2000, respectively, which it believes approximates arm's-length costs.

**(15) Transactions with Inverness Medical Technology, Inc. and Affiliates (Continued)**

The charges by IMT to IMI, which are included in the respective captions in the accompanying consolidated statements of operations, are made up of the following:

| | 2001(i) | 2000 |
|---|---|---|
| Cost of sales | $ 207,825 | $ 245,431 |
| Research and development | 23,272 | 36,810 |
| Sales and marketing | 1,365,547 | 1,495,455 |
| General and administrative | 1,436,831 | 955,365 |
| | $3,033,475 | $2,733,061 |

(i) Through November 21, 2002, the date of split-off and merger.

*(b) Loans from IMT*

In February 1997, in connection with IMI's purchase of the nutritional supplement product line from American Home Products (now known as Wyeth), IMI borrowed $2,000,000 from IMT. Interest was accruing at an annual rate of 6.5%. Interest expense on this note, which is included in the accompanying statements of operations, was $115,397 and $130,356 during 2001 and 2000, respectively.

At December 31, 2000, the Company's Irish subsidiary, CDIL, had a note payable balance plus accrued interest totaling approximately $2,208,274 due to IMT under a loan agreement originally dated July 1, 1997, as amended. Interest was accruing at an annual rate of 9%. Interest expense on this note, which is included in the accompanying statements of operations, was $182,844 and $164,665 during 2001 and 2000, respectively.

As discussed in Note 1, upon the split-off and merger in November 2001, IMT and its affiliates forgave all outstanding balances due from the Company and the Company's affiliates. The forgiveness of this indebtedness, or $10,368,735, was recorded as a component of the capital contribution from IMT.

*(c) Transition Services Agreement with IMT*

Prior to the split-off from IMT, the Company entered into transition services agreements, whereby it would provide certain transition services to IMT and IMT affiliates for an agreed-upon period of time and service fee. Transition services primarily included management services provided by IMI and product packaging services provided by CDIL related to certain diabetes businesses and products. Since the split-off from IMT, IMI has charged approximately $1,910,110 and $180,907 during 2002 and 2001, respectively, in transition service fees to IMT, which it believes to approximate arm's-length costs. These fees reduced the Company's general and administrative expenses during the respective periods. Since the split-off from IMT, CDIL has generated $5,108,192 and $1,058,908 during 2002 and 2001, respectively, in net product sales under its packaging service contract with an affiliate of IMT. The transition services provided by IMI and CDIL terminated in February 2003 and July 2002, respectively.

*(d) Discontinued Operations*

Pursuant to the Merger Agreement and related agreements in connection with the split-off from IMT, the Company transferred to IMT those entities or businesses that conduct business in the diabetes

(15) Transactions with Inverness Medical Technology, Inc. and Affiliates (Continued)

segment, principally the Can-Am subsidiary of IMI and the diabetes business of IMB. As discussed in Note 1, the accompanying consolidated financial statements reflect the transfer of the diabetes businesses by the Company as discontinued operations.

The accompanying consolidated statements of operations include income (loss) from discontinued operations as follows:

| | 2001(i) | 2000 |
|---|---|---|
| Net product sales | $30,748,823 | $33,478,566 |
| Cost of sales | 22,605,542 | 23,108,414 |
| Gross profit | 8,143,281 | 10,370,152 |
| Operating expenses | 6,634,612 | 8,755,407 |
| Operating income | 1,508,669 | 1,614,745 |
| Other expenses, net | (415,929) | (1,083,989) |
| Income before income taxes and extraordinary item | 1,092,740 | 530,756 |
| Provision for income taxes | 761,613 | 1,128,540 |
| Income (loss) before extraordinary item | 331,127 | (597,784) |
| Extraordinary loss from early extinguishment of debt | (273,232) | — |
| Net income (loss) from discontinued operations | $ 57,895 | $ (597,784) |

(i) Through November 21, 2001, the date of the split-off and merger

(16) Valuation and Qualifying Accounts

The Company has established reserves against accounts receivable for doubtful accounts, product returns, discounts and other allowances. The activity in the table below includes all accounts receivable reserves. Provisions for doubtful accounts are recorded as a component of selling, general and administrative expenses. Provisions for returns, discounts and other allowances are charged against net product sales. The following table sets forth activities in the Company's accounts receivable reserve accounts:

| | Balance at Beginning of Period | Provision | Amounts Charged Against Reserves | Balance at End of Period |
|---|---|---|---|---|
| Year ended December 31, 2000 | $2,235,357 | $ 9,339,784 | $ (9,833,426) | $1,741,715 |
| Year ended December 31, 2001 | 1,741,715 | 10,590,563 | (9,737,141) | 2,595,137 |
| Year ended December 31, 2002 | 2,595,137 | 19,979,395 | (15,527,258) | 7,047,274 |

# NOTES

# Company and Shareholder Information

## MANAGEMENT

**Ron Zwanziger**
Chairman of the Board,
Chief Executive Officer,
and President

**David Scott, Ph.D.**
Chief Scientific Officer

**Jerry McAleer, Ph.D.**
Vice President,
Research & Development

**Anthony Bernardo**
Vice President and
Chief Operating Officer

**Jack Wilkens**
Vice President,
Consumer Diagnostics

**David Toohey**
Vice President,
Professional Diagnostics

**Duane L. James**
Vice President of Finance
and Treasurer

**John Yonkin**
U.S. Sales & Marketing,
Vice President

**Doug Shaffer**
U.S. Operations,
Vice President

**Paul T. Hempel**
Secretary and General
Counsel

## DIRECTORS

**Ron Zwanziger**
Chairman of the Board,
Chief Executive Officer,
and President
*Inverness Medical Innovations, Inc.*

**Ernest A. Carabillo, Jr.**[3]
President,
*EXPERTech Associates, Inc.*

**Carol R. Goldberg**[1,3]
President,
*The AVCAR Group, Ltd.*

**Robert P. Khederian**[2,3]
Chairman,
*Belmont Capital*
*Provident Corporate Finance*

**John F. Levy**[2,3]
formerly President and
Chief Executive Officer
*Waban, Inc.*

**Jerry McAleer, Ph.D.**
Vice President,
Research & Development
*Inverness Medical Innovations, Inc.*

**David Scott, Ph.D.**
Chief Scientific Officer,
*Inverness Medical Innovations, Inc.*

**Peter Townsend**[2,3]
formerly Chief Executive
Officer
*Enviromed, plc*

**John A. Quelch**[3]
Senior Associate Dean for
International Development
*Harvard Business School*

**Alfred M. Zeien**[1,3]
formerly Chairman of the
Board and Chief Executive
Officer
*The Gillette Company*

1 Member of the Compensation Committee
2 Member of the Audit Committee
3 Member of the Nominating Committee

## SHAREHOLDER INFORMATION

### Certified Public Accountants

**Ernst & Young LLP**
200 Clarendon Street
Boston, MA 02116-5072

### Transfer Agent

**Equiserve**
P.O. Box 9187
Canton, MA 02021-9187

### Legal Counsel

**Goodwin Procter LLP**
Exchange Place
Boston, MA 02109

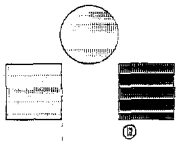
**Foley Hoag LLP**
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210-2600

**Allen & Overy**
One New Change
London EC4M 9QQ

### Annual Meeting

**Wednesday, May 21, 2003**
**At 12:30 PM**

**Goodwin Procter LLP**
Exchange Place
53 State Street
Boston, MA 02109



inverness
medical
innovations

Shareholder Relations – Inverness Medical Innovations, Inc.
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## Notes and Disclaimers

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The abstract logo is a registered trademark of Inverness Medical Innovations, Inc.

The company's shares, first offered to the public in 2001, are traded on the American Stock Exchange under the symbol IMA.

Please visit the company website at www.invernessmedical.com for current news and information.

The company's stock option plan was adopted on July 31, 2001 and, as of December 31, 2002, there were 838,279 shares of common stock available for the granting of options thereunder.

This Annual Report and the attached Annual Report on Form 10-K contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Readers can identify these statements by forward-looking words such as "may," "could," "should," "would," "intend," "will," "expect," "anticipate," "believe," "estimate," "continue" or similar words. There are a number of important factors that could cause actual results of Inverness Medical Innovations, Inc. and its subsidiaries to differ materially from those indicated by such forward-looking statements. These factors include, but are not limited to, difficulties in integrating acquired entities and operating them profitably, the inability to consummate proposed acquisition transactions, difficulties in obtaining financing on satisfactory terms, manufacturing and shipping problems or delays, the risks of product defects and failure to meet strict regulatory requirements both in the United States and abroad, intense competition and economic trends, which could reduce our market share, limit our ability to increase market share or decrease our operating margins as a result of competitive pricing pressures, as well as other risk factors detailed in the attached Annual Report on Form 10-K and other risk factors identified from time to time in our periodic filings with the Securities and Exchange Commission. Readers should carefully review the factors discussed in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations–Certain Factors Affecting Future Results" and "Special Statement Regarding Forward-Looking Statements" beginning on pages 38 and 53, respectively, in the attached Annual Report on Form 10-K 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.