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

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# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549**

# FORM 10-K/A

**(Amendment No. 1)**

**(Mark One)**

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

**For the fiscal year ended December 31, 2003**

**or**

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

**For the transition period from _____ to _____**

**Commission file number 000-16789**

# INVERNESS MEDICAL INNOVATIONS, INC.

(Exact Name of Registrant as Specified in Its Charter)

| **Delaware** | **04-3565120** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (I.R.S. Employer Identification No.) |
| **51 Sawyer Road, Suite 200, Waltham, Massachusetts** | **02453** |
| (Address of principal executive offices) | (Zip Code) |

**(781) 647-3900**

(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

**DOCUMENTS INCORPORATED BY REFERENCE**

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

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**EXPLANATORY NOTE**

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

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

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

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

**PART I**

*This annual report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. You can identify these statements by forward-looking words such as "may," "could," "should," "would," "intend," "will," "expect," "anticipate," "believe," "estimate," "continue" or similar words. You should read statements that contain these words carefully because they discuss our future expectations, contain projections of our future results of operations or of our financial condition or state other "forward-looking" information. There may be events in the future that we are not able to predict accurately or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. We caution investors that all forward-looking statements involve risks and uncertainties, and actual results may differ materially from those we discuss in this report. There are a number of important factors that could cause our actual results to differ materially from those projected by such forward-looking statements. These factors include, but are not limited to, the risk factors*

*detailed in this report and other risk factors identified from time to time in our periodic filings with the Securities and Exchange Commission. You should carefully review the factors discussed in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations Certain Factors Affecting Future Results" and "Special Statement Regarding Forward-Looking Statements" beginning on pages 50 and 65, respectively, in this report and should not place undue reliance on our forward-looking statements. These forward-looking statements were based on information, plans and estimates at the date of this report. We undertake no obligation to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events or other changes.*

*Unless the context requires otherwise, references in this annual report on Form 10-K to "we," "us," "our," or "our company" refer to Inverness Medical Innovations, Inc. and its subsidiaries, and their respective predecessor entities for the applicable periods, considered as a single enterprise.*

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

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

**ITEM 1. BUSINESS**

**OVERVIEW**

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

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

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

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

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

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

**RECENT DEVELOPMENTS**

*Private Placement of 8 3/4% Senior Subordinated Notes*

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

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

**BUSINESS SEGMENTS AND GEOGRAPHIC AREA**

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

**Industry**

*Consumer Products*

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

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

*Professional Diagnostics*

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

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

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

**Products**

*Consumer Products*

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

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

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

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

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

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

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

*Professional Diagnostic Products*

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

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

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

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

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

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

**Marketing and Sales**

*Consumer Products*

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

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

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

*Professional Diagnostic Products*

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

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

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

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

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

**Manufacturing**

*Consumer Products*

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

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

We are currently using the Bedford facility pursuant to an agreement with Unilever entered into in connection with our acquisition of the Unipath business in 2001. For more information regarding our use of the Bedford facility and the risks associated with our arrangement to use this facility see "Certain Factors Affecting Future Results We could experience significant manufacturing delays, disruptions to our ongoing research and development and increased production costs if Unilever is unable to successfully assign or sublease to us the lease for the multi-purpose facility that we currently use in Bedford, England."

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

*Professional Diagnostic Products*

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

**Research and Development**

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

**Foreign Operations**

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

**Competition**

*General*

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

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

*Consumer Products*

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



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

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

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

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

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

*Professional Diagnostic Products*

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



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

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

**Patents and Proprietary Technology; Trademarks**

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

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

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



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

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

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

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

**Government Regulation**

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

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

changes are not uncommon due to advances in basic research.

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



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

**Product Liability and Limited Insurance Coverage**

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

**Employees**

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

## ITEM 2. DESCRIPTION OF PROPERTY

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

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

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

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

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

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

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



**ITEM 3. LEGAL PROCEEDINGS**

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

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

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

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

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

*Other Pending and Potential Litigation and Proceedings*

Because of the nature of our business, we may be subject at any particular time to consumer product claims or various other lawsuits arising in the ordinary course of our business, including employment matters, and expect that this will continue to be the case in the future. Such lawsuits generally seek damages, sometimes in substantial amounts, for personal injuries or other commercial or employment claims. An adverse ruling in such a lawsuit could have a material adverse effect on our sales, operations or financial performance. In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties. We have approximately 15 lawsuits pending around the world against competitors whom we believe to be selling products that infringe our propriety rights, including a suit against Acon Laboratories. These suits can be expensive and result in counterclaims challenging the validity of our patents and other rights.

We have discussed in prior periodic reports an action in London by approximately 65 consumers claiming defects in Unipath's Persona contraceptive device, negligence and breach of contract, all allegedly leading to unwanted pregnancies by the claimants in or prior to 1998. Because this case is insured, in the aggregate, by Unilever's product liability insurance up to 50 million British pounds sterling or more, depending on when the events giving rise to the consumers' suit occurred, we do not



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

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

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

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



**PART II**

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

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

| | High | Low |
|---|---|---|

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

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

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

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

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

**ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA**

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

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

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

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

**(in thousands, except per share data)**

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

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

(1)

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

(2)

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

(3)

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

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

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

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

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

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

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

**(in thousands, except per share data)**

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

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

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

### Overview

*General*

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

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

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

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

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

*Our History*

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

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

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

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

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

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

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

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

**Restatements of 2003 and 2002 Financial Statements**

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

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

**(in thousands, except per share data)**

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

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

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

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

**Results of Operations**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Cumulative Effect of a Change in Accounting Principle.** On January 1, 2002, we adopted Statement of Financial Accounting Standards, or SFAS, No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 142 requires annual impairment tests to be performed on all reporting units, as defined in the statement, with carrying values for goodwill. Based on the results of an independent appraisal obtained on the nutritional supplements business that we acquired in 1997, we recorded an impairment charge of $12.1 million to write-off the carrying value of the goodwill related to that business on January 1, 2002. This impairment charge was recorded as a cumulative effect of a change in accounting principle. There were no charges due to a change in accounting principle during 2003.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**Charge Related to Asset Impairment.** In the first quarter of 2002, we recorded a non-cash impairment charge of $12.7 million to write-off a portion of the value that was assigned to trademarks and brand names related to certain of our nutritional supplement lines that we acquired in 1997. This charge was recorded in connection with the results of a separate impairment review performed on the carrying value of the goodwill related to such nutritional supplement lines, as discussed below in the caption "Cumulative Effect of a Change in Accounting Principle". See also note 5 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. No impairment charge was recorded during 2001.

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

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

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

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

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

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

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

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

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

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

**Cumulative Effect of a Change in Accounting Principle.** On January 1, 2002, we adopted Statement of Financial Accounting Standard, or SFAS, No. 142, *Goodwill and Other Intangible Assets*. SFAS No. 142 requires annual impairment tests to be performed on all reporting units, as defined in the statement, with values recorded for goodwill. Based on the results of an independent appraisal obtained on the nutritional supplements business that we acquired in 1997, we recorded an impairment charge of $12.1 million to write-off the carrying value of the goodwill related to that business on January 1, 2002. This impairment charge was recorded as a cumulative effect of a change in accounting principle. See note 5 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. There were no charges due to a change in accounting principle in 2001.

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

**Supplementary Quarterly Financial Information**

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

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

**(in thousands, except per share data)**

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

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

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

Report on Form 10-K.

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

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

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

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

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

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

**Liquidity and Capital Resources**

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

*Changes in Cash Position*

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

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

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

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

*Investing Activities*

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

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

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

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

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

*Financing Activities*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*Income Taxes*

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

**Off-Balance Sheet Arrangements**

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

**Contractual Obligations**

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

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

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

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

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

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

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

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

**Critical Accounting Policies**

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

*Revenue Recognition*

We primarily recognize revenue when the following four basic criteria have been met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed and determinable; and (4) collection is reasonably assured.

The majority of our revenues are derived from product sales. We generally do not enter into arrangements with multiple element deliverables. We recognize revenue upon title transfer of the products to third-party customers, less a reserve for estimated product returns and allowances. Determination of the reserve for estimated product returns and allowances is based on our management's analyses and judgments regarding certain conditions, as discussed below in the critical accounting policy "Use of Estimates for Sales Returns and Other Allowances and Allowance for Doubtful Accounts." Should future changes in conditions prove management's conclusions and judgments on previous analyses to be incorrect, revenue recognized for any reporting period could be adversely affected.

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

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

Sales arrangements with customers for our consumer products generally require us to accept product returns. From time to time, we also enter into sales incentive arrangements with our retail customers, which generally reduce the sale prices of our products. As a result, we must establish allowances for potential future product returns and claims resulting from our sales incentive arrangements against product revenue recognized in any reporting period. Calculation of these allowances requires significant judgments and estimates. When evaluating the adequacy of the sales returns and other allowances, our management analyzes historical returns, current economic trends, and changes in customer demand and acceptance of our products. Material differences in the amount and timing of our product revenue for any reporting period may result if changes in conditions arise that would require management to make different judgments or utilize different estimates.

Our total provision for sales returns and other allowances related to sales incentive arrangements amounted to approximately $46.2 million, $44.2 million and $4.8 million in 2003, 2002 and 2001, respectively, which had been recorded against product sales to derive our net product sales.

Similarly, our management must make estimates regarding uncollectible accounts receivable balances. When evaluating the adequacy of the allowance for doubtful accounts, management analyzes specific accounts receivable balances, historical bad debts, customer concentrations, customer credit-worthiness, current economic trends and changes in our customer payment terms and patterns. Our accounts receivable balance was $55.4 million and $36.9 million, net of allowances for doubtful accounts of $797,000 and $871,000, as of December 31, 2003 and 2002, respectively.

*Valuation of Inventories*

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

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

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

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

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

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

Valuation of Goodwill

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

Valuation of Other Long-Lived Tangible and Intangible Assets

Factors we generally consider important which could trigger an impairment review on the carrying value of other long-lived tangible and intangible assets include the following: (1) significant underperformance relative to expected historical or projected future operating results; (2) significant changes in the manner of our use of acquired assets or the strategy for our overall business; (3) underutilization of our tangible assets; (4) discontinuance of product lines by ourselves or our customers; (5) significant negative industry or economic trends; (6) significant decline in our stock price for a sustained period; (7) significant decline in our market capitalization relative to net book value; and (8) goodwill impairment identified during an impairment review under SFAS No. 142. Although we believe that the carrying value of our long-lived tangible and intangible assets was realizable as of December 31, 2003, future events could cause us to conclude otherwise.

*Accounting for Income Taxes*

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

Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have recorded a valuation allowance of $66.7 million as of December 31, 2003 due to uncertainties related to the future benefits, if any, from our deferred tax assets related primarily to our U.S. businesses and certain foreign net operating losses and tax credits. The valuation allowance is based on our estimates of taxable income by jurisdiction in which we operate and the period over which our deferred tax assets will be recoverable. In the event that actual results differ from these estimates or we adjust these estimates in future periods, we may need to establish an additional valuation allowance or reduce our current valuation allowance which could materially impact our tax provision.

*Legal Contingencies*

Because of the nature of our business, we may from time to time be subject to consumer product claims or various other lawsuits arising in the ordinary course of our business, and we expect this will continue to be the case in the future. These lawsuits generally seek damages, sometimes in substantial amounts, for personal injuries or other commercial claims. In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties, which can be expensive and can result in counterclaims against us. We are currently involved in certain legal proceedings, as discussed in "Item 3. Legal Proceedings" in this Annual Report on Form 10-K. We do not accrue for potential losses on legal proceedings where our company is the defendant when we are not able to quantify our potential liability, if any, due to uncertainty as to the nature, extent and validity of the claims against us, uncertainty as to the nature and extent of the damages or other relief sought by the plaintiff and the complexity of the issues involved. Our potential liability, if any, in a particular case may become quantifiable and probable as the case progresses, in which case we will begin accruing for the expected loss.

In addition, in the section of this Annual Report on Form 10-K titled "Item 3. Legal Proceedings," we have reported on certain legal proceedings as to which we do not believe a final ruling against us could have a material adverse impact on our financial position and operations. To the extent that unanticipated facts or circumstances arise that cause us to change this assessment with respect to any matter, our future results of operations and financial position could be materially affected.

**Recently Issued Accounting Standards**

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

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

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

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

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

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

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

**Certain Factors Affecting Future Results**

There are various risks, including those described below, which may materially impact your investment in our company or may in the future, and, in some cases already do, materially affect us and our business, financial condition and results of operations. You should carefully consider these factors with respect to your investment in our securities. This section includes or refers to certain forward-looking statements; you should read the explanation of the qualifications and limitations on such forward-looking statements beginning on pages 2 and 65 of this report.

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

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

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

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

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

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

impair our ability to obtain additional financing;

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

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

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

competitors. We cannot be certain that our cash flow will be sufficient to allow us to pay principal and interest on our debt and meet our other obligations. If our cash flow and capital resources prove inadequate, we could face substantial liquidity problems and might be required to dispose of material assets or operations, restructure or refinance our debt, including the notes, seek additional equity capital or borrow more money. We cannot guarantee that we will be able to do so on terms acceptable to us. In addition, the terms of existing or future debt agreements, including the credit agreement governing our senior credit facility and the indenture governing the senior subordinated notes, may restrict us from adopting any of these alternatives.

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

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

incur additional indebtedness;

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

acquire other businesses;

make investments;

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

enter into transactions with affiliates;

raise additional capital;

make capital or finance lease expenditures;

dispose of or encumber assets; and

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

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

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

As of February 29, 2004, we had approximately $12.0 million of indebtedness outstanding under our various credit facilities and approximately $51.5 million of additional borrowing capacity under these credit facilities. The agreements governing these credit facilities subject us to various financial and other covenants with which we must comply on an ongoing or periodic basis. These include covenants pertaining to fixed charge coverage, capital expenditures, various leverage ratios, minimum EBITDA, total net worth and minimum cash requirements. If we violate any of these covenants, there may be a material adverse effect on us. Most notably, our outstanding debt under one or more of our credit facilities could become immediately due and payable, our lenders could proceed against any collateral securing such indebtedness, and our ability to borrow additional funds in the future may be limited.

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

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

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

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

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

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

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

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

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

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

coordinating geographically separate organizations.

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

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

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

the inability to complete the acquisition or investment;

disruption of our ongoing businesses and diversion of management attention;

difficulties in integrating the acquired entities, products or technologies;

difficulties in operating the acquired business profitably;

the inability to achieve anticipated synergies, cost savings or growth opportunities;

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

difficulties in transitioning key customer, distributor and supplier relationships;

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

unanticipated costs.

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

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

use of significant amounts of cash;

the incurrence of debt;

the assumption of significant liabilities;

unfavorable financing terms;

large one-time expenses; and

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

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

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

In connection with the accounting for our acquisitions of the Unipath business, Wampole, Ostex, ABI and the Abbott rapid diagnostics product lines, we have recorded a significant amount of goodwill and other intangible assets. Under current accounting guidelines, we must assess, at least annually and potentially more frequently, whether the value of goodwill and other intangible assets has been impaired. Any reduction or impairment of the value of goodwill or other intangible assets will result in a charge against earnings which could materially adversely affect our results of operations in future periods.

**We could experience significant manufacturing delays, disruptions to our ongoing research and development and increased production costs if Unilever is unable to successfully assign or sublease to us the lease for the multi-purpose facility that we currently use in Bedford, England.**

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

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

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

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

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

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

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

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

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

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

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

Our facilities and manufacturing techniques generally must conform to standards that are established by government agencies, including those of European and other foreign governments, as well as the FDA, and, to a lesser extent, the U.S. Drug Enforcement Administration, or the DEA, and local health agencies. These regulatory agencies may conduct periodic audits of our facilities to monitor our compliance with applicable regulatory standards. If a regulatory agency finds that we fail to comply with the appropriate regulatory standards, it may impose fines on us or if such a regulatory agency determines that our non-compliance is severe, it may close our facilities. Any adverse action by an applicable regulatory agency could impair our ability to produce our products in a cost-effective and timely manner in order to meet our customers' demands. These regulatory agencies may also impose new or enhanced standards that would increase our costs as well as the risks associated with non-compliance. For example, we anticipate that the FDA may soon finalize and implement "good manufacturing practice," or GMP, regulations for nutritional supplements. GMP regulations would require supplements to be prepared, packaged and held in compliance with certain rules, and might require quality control provisions similar to those in the GMP regulations for drugs. While our manufacturing facilities for nutritional supplements have been subjected to, and passed, third party inspections against anticipated GMP standards, the ongoing compliance required in the event that GMP regulations are adopted would involve additional costs and would present new risks associated with any failure to comply with the regulations in the future.

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

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

**Our sales of branded nutritional supplements have been trending downward since 1998 due to the maturity of the market segments they serve and the age of that product line and we may experience further declines in sales of those products.**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- increased costs or reduced revenue as a result of movements in foreign currency exchange rates;
- decreased liquidity resulting from longer accounts receivable collection cycles typical of foreign countries;
- lower productivity resulting from difficulties managing our sales, support and research and development operations across many countries;
- lost revenues resulting from difficulties associated with enforcing agreements and collecting receivables through foreign legal systems;
- lost revenues resulting from the imposition by foreign governments of trade protection measures;
- higher cost of sales resulting from import or export licensing requirements;
- lost revenues or other adverse affects as a result of economic or political instability in or affecting foreign countries in which we sell our products or operate; and
- adverse effects resulting from changes in foreign regulatory or other laws affecting the sales of our products or our foreign operations.

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

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

and our Orgenics professional diagnostic products have always been sold exclusively outside of the United States. Because of our foreign operations and foreign sales, we face exposure to movements in foreign currency exchange rates. Our primary exposures are related to the operations of our European subsidiaries. These exposures may change over time as business practices evolve and could result in increased costs or reduced revenue and could impact our actual cash flow.

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

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

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

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

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

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

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

Also, the possibility of patent disputes with competitors holding foreign patent rights may limit or delay expansion possibilities for our diagnostics businesses in certain foreign jurisdictions. In addition, many of our existing or potential competitors have or may have substantially greater research and

development capabilities, clinical, manufacturing, regulatory and marketing experience and financial and managerial resources.

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

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

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

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

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

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

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

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

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

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

assert claims of infringement;

enforce our patents;

protect our trade secrets or know-how; or

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

Currently, we have initiated a number of lawsuits against competitors who we believe to be selling products that infringe our proprietary rights. These current lawsuits and any other lawsuits that we initiate could be expensive, take significant time and divert management's attention from other business concerns. Litigation also puts our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing. Additionally, we may provoke third parties to assert claims against us.

Patent law relating to the scope of claims in the technology fields in which we operate is still evolving and, consequently, patent positions in our industry are generally uncertain. We may not prevail in any of these suits and the damages or other remedies awarded, if any, may not be commercially valuable. During the course of these suits, there may be public announcements of the results of hearings, motions and other interim proceedings or developments in the litigation. If securities analysts or investors perceive any of these results to be negative, our stock price could decline.

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

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

years. In addition, Mr. Ron Zwanziger, our Chairman, Chief Executive Officer and President, and two of our senior scientists, Dr. David Scott and Dr. Jerry McAleer, have entered into consulting agreements with IMT that impose similar restrictions. Further, our license agreement with IMT prevents us from using any of the licensed technology in the field of diabetes. As a result of these restrictions, we cannot pursue opportunities in the field of diabetes.

**We are obligated to indemnify IMT and others for liabilities and could be required to pay IMT and others amounts that we may not have.**

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

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

While no claims for indemnification have yet been made, or may ever be made, we are unable to predict the amount, if any, that may be required for us to satisfy our indemnification obligations under these agreements. However, if claims are made for indemnification and we are liable for such claims, the amount could be substantial. In such an event, we may not have sufficient funds available to satisfy our potential indemnification obligations. In addition, we may be unable to obtain the funds on terms satisfactory to us, if at all. If we are unable to obtain the necessary funds, we will need to consider other alternatives, including sales of assets, to raise necessary funds.

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

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

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

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

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

the timing of new product announcements and introductions by us and our competitors;

market acceptance of new or enhanced versions of our products;

changes in manufacturing costs or other expenses;

competitive pricing pressures;

the gain or loss of significant distribution outlets or customers;

increased research and development expenses;

the timing of any future acquisitions;

general economic conditions; or

general stock market conditions or other economic or external factors.

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

On November 21, 2001, we were split-off from IMT and became an independent, publicly owned company as part of a transaction by which IMT was acquired by Johnson & Johnson. Prior to that time, we had been a majority owned subsidiary of IMT, and the businesses that we acquired in connection with the restructuring that preceded the split-off represented approximately 20% of IMT's net product sales during the calendar quarter concluded immediately prior to the split-off. The historical financial information relating to any periods beginning prior to November 21, 2001, included in our reports filed with the SEC, report on time periods prior to the split-off and reflect the operating history of our businesses when we were a part of IMT. As a result, the financial information may not reflect what our results of operations, financial position and cash flows would have been had we been a separate, stand-alone company during those periods. This financial information also may not reflect what our results of operations, financial position and cash flows will be in the future. This is not only related to the various risks associated with the fact that we have not been a stand-alone company for a long period of time, but also because:

various adjustments and allocations have been made to produce these financial statements because IMT did not account for us as a single stand-alone business for those periods presented; and

the information, to the extent it does not report on a period ending on or after November 21, 2001, does not reflect many significant changes that occurred in our financial condition, capital structure and operations as a result of our separation from IMT.

The adjustments and allocations we made in preparing the financial information for any periods beginning prior to November 21, 2001 may not appropriately reflect our operations during those periods as if we had operated as a stand-alone company.

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

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

**SPECIAL STATEMENT REGARDING FORWARD-LOOKING STATEMENTS**

This report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. You can identify these statements by forward-looking words such as "may," "could," "should," "would," "intend," "will," "expect," "anticipate," "believe," "estimate," "continue" or similar words. You should read statements that contain these words carefully because they discuss our future expectations, contain projections of our future results of operations or of our financial condition or state other "forward-looking" information. There may be events in the future that we are not able to predict accurately or control and that may cause our actual results to differ materially from the expectations we describe in our forward-looking statements. We caution investors that all forward-looking statements involve risks and uncertainties, and actual results may differ materially from those we discuss in this report. These differences may be the result of various factors, including those factors described in the "Certain Factors Affecting Future Results" section in this report and other risk factors identified from time to time in our periodic filings with the SEC. Some important additional factors that could cause our actual results to differ materially from those projected in any such forward-looking statements are as follows:

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

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

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

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

manufacturing interruptions, delays or capacity constraints or lack of availability of alternative sources for components for our products, including our ability to successfully maintain relationships with suppliers, or to put in place alternative suppliers on terms that are acceptable to us;

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

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

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

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

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

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

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

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

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

### Interest Rate Risk

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

Our investing strategy, to manage interest rate exposure, is to invest in short-term, highly liquid investments. Our investment policy also requires investment in approved instruments with an initial maximum allowable maturity of eighteen months and an average maturity of our portfolio that should not exceed six months, with at least $500,000 cash available at all times. Currently, our short-term investments are in money market funds with original maturities of 90 days or less. At December 31, 2003, our short-term investments approximated market value.

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

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

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

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

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

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

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

**Foreign Currency Risk**

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

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

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

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

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

**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

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

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

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

**ITEM 9A. CONTROLS AND PROCEDURES**

*Conclusions regarding the effectiveness of our disclosure controls and procedures*

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

*Changes in internal control over financial reporting*

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

## PART III

### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

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

### ITEM 11. EXECUTIVE COMPENSATION

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

### ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

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

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

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

### ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

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

**PART IV**

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

(a)

1. Financial Statements.

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


| | |
|---|---|
| Report of Independent Auditors | F-2 |
| Report of Independent Public Accountants | F-4 |
| Consolidated Statements of Operations for the Years Ended December 31, 2003 (restated), 2002 (restated) and 2001 | F-5 |
| Consolidated Balance Sheets as of December 31, 2003 (restated) and 2002 (restated) | F-6 |
| Consolidated Statements of Stockholders' Equity and Comprehensive Income (Loss) for the Years Ended December 31, 2003 (restated), 2002 (restated) and 2001 | F-7 |
| Consolidated Statements of Cash Flows for the Years Ended December 31, 2003 (restated), 2002 (restated) and 2001 | F-10 |
| Notes to Consolidated Financial Statements | F-13 |


2. Financial Statement Schedules.

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

3. Exhibits.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

| | |
|---|---|
| **31.1 | Certification by Chief Executive Officer Pursuant to Section 302 of the Sarbanes |
| **31.2 | Certification by Chief Financial Officer Pursuant to Section 302 of the Sarbanes |
| **32.1 | Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes |

* Previously filed.

** Filed herewith.

\+ Portions of this exhibit have been omitted pursuant to a request for confidential treatment.

(b) *Reports on Form 8-K*

On October 9, 2003 we filed a Current Report on Form 8-K dated September 30, 2003 (Item 2) in connection with our acquisition of certain assets from Abbott Laboratories.

On November 5, 2003 we filed a Current Report on Form 8-K dated November 5, 2003 (Item 12) in connection with our press release relating to our financial results for the third quarter of 2003.

On November 10, 2003 we filed a Current Report on Form 8-K/A (Amendment No. 1) dated August 27, 2003 (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 Applied Biotech, Inc.

On November 20, 2003 we filed a Current Report on Form 8-K/A (Amendment No. 1) dated September 30, 2003 (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 certain assets from Abbott Laboratories.

On December 17, 2003 we filed a Current Report on Form 8-K dated December 10, 2003 (Item 5) in connection with our entry into manufacturing and supply agreement with Warner-Lambert Company, LLC.

**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: April 22, 2004 By: /s/ RON ZWANZIGER

Ron Zwanziger

*Chairman, Chief Executive Officer and President*

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 | Chief Executive Officer, President and Director (Principal Executive Officer) | April 22, 2004 |
| /s/ CHRISTOPHER J. LINDOP<br>Christopher J. Lindop | Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) | April 22, 2004 |
| /s/ ERNEST A. CARABILLO, JR.<br>Ernest A. Carabillo, Jr. | Director | April 22, 2004 |
| /s/ CAROL R. GOLDBERG<br>Carol R. Goldberg | Director | April 22, 2004 |
| /s/ ROBERT P. KHEDERIAN<br>Robert P. Khederian | Director | April 22, 2004 |
| /s/ JOHN F. LEVY<br>John F. Levy | Director | April 22, 2004 |
| /s/ JERRY MCALEER<br>Jerry McAleer | Director | April 22, 2004 |
| /s/ JOHN A. QUELCH<br>John A. Quelch | Director | April 22, 2004 |
| /s/ DAVID SCOTT<br>David Scott | Director | April 22, 2004 |

| Signature | Title | Date |
|---|---|---|
| /s/ PETER TOWNSEND<br>Peter Townsend | Director | April 22, 2004 |
| /s/ ALFRED M. ZEIEN<br>Alfred M. Zeien | Director | April 22, 2004 |

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**

**CONSOLIDATED FINANCIAL STATEMENTS**

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**REPORT OF INDEPENDENT AUDITORS**

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

We have audited the accompanying consolidated balance sheets of Inverness Medical Innovations, Inc. and Subsidiaries (the "Company") as of December 31, 2003 and 2002, and the related consolidated statements of operations, stockholders' equity and comprehensive income (loss), and cash flows for the two years ended December 31, 2003. 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 audits. The consolidated financial statements of the Company as of December 31, 2001, and for the year then ended 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 below.

We conducted our audits in accordance with auditing standards generally accepted in the United States of America. 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 2003 and 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, 2003 and 2002, and the consolidated results of their operations and their cash flows for the two years ended December 31, 2003, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2(q) of the consolidated financial statements, the Company has restated its financial statements as of and for the years ended December 31, 2003 and 2002.

As discussed above, the financial statements of the Company as of December 31, 2001 and for the year then ended were audited by other auditors who have ceased operations. 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,* Statement of Financial Accounting Standards ("SFAS") No. 145, *Rescission of FASB Statement No. 4, 44 and 64, Amendment of FASB Statement No. 13 and Technical Corrections,* and SFAS No. 142, *Goodwill and Other Intangible Assets*. The 2001 consolidated financial statements have been adjusted (i) to reclassify certain amounts between net product sales and sales and marketing expenses in the statement of operations, as required by EITF Issue No. 01-09, and (ii) to reclassify certain amounts between extraordinary loss and other income (expense), net, as required by SFAS No. 145. Note 5 of the consolidated financial statements discloses the effect of adjusting the statement of operations to exclude goodwill amortization for 2001, as required by SFAS No. 142.

We audited the adjustments that were applied to reclassify certain amounts between net product sales and sales and marketing expenses in the statement of operations for 2001. 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. We also audited the adjustments that were applied to reclassify amounts between the extraordinary loss



on the early extinguishment of debt and other income (expense), net, in the statement of operations for 2001. Our procedures included (i) agreeing the adjusted amounts of other income (expense), net, to the Company's underlying accounting records obtained from management and (ii) testing the mathematical accuracy of the adjusted amounts of other income (expense), net. Our audit procedures with respect to goodwill disclosures in Note 5 relating to 2001 included (i) agreeing the previously reported net income (loss) and the adjustments to reported net income (loss) representing amortization expense recognized in 2001 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 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 for the year then ended taken as a whole.

**/s/ BDO Seidman, LLP**

Boston, Massachusetts
February 17, 2004 (except for the restatements
discussed in Note 2(q), as to which the date
is April 19, 2004)



*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, 2003.*** *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**

**(in thousands, except per share amounts)**

| | 2003 | 2002 | 2001 |
|---|---|---|---|
| | (restated) | (restated) | |

| | 2003 | 2002 | 2001 |
|---|---|---|---|
| Net product sales | $ 286,984 | $ 200,399 | $ 47,268 |
| License revenue | 9,728 | 6,405 | |
| **Net Revenue** | 296,712 | 206,804 | 47,268 |
| Cost of sales | 168,120 | 114,653 | 26,662 |
| **Gross profit** | 128,592 | 92,151 | 20,606 |
| Operating expenses: | | | |
| Purchased in-process research and development (Note 4(f)) | | | 6,980 |
| Research and development | 24,280 | 14,471 | 1,810 |
| Sales and marketing | 51,705 | 39,544 | 8,018 |
| General and administrative | 35,452 | 28,066 | 11,702 |
| Charge related to asset impairment (Note 5) | | 12,682 | |
| Stock-based compensation (1) (Notes 1 and 12(c)) | 447 | 10,625 | 10,441 |
| Total operating expenses | 111,884 | 105,388 | 38,951 |
| **Operating income (loss)** | 16,708 | (13,237) | (18,345) |
| Interest expense, including amortization of discounts (Note 6) | (9,711) | (15,069) | (2,294) |
| Other income (expense), net | 6,441 | 9,114 | (2,016) |
| **Income (loss) from continuing operations before income taxes** | 13,438 | (19,192) | (22,655) |
| Provision for income taxes | 1,169 | 2,683 | 2,134 |
| **Income (loss) from continuing operations** | 12,269 | (21,875) | (24,789) |
| Income from discontinued operations, net of taxes (Note 16(d)) | | | 58 |
| **Income (loss) before cumulative effect of a change in accounting principle** | 12,269 | (21,875) | (24,731) |
| Cumulative effect of a change in accounting principle (Note 5) | | (12,148) | |
| **Net income (loss)** | $ 12,269 | $ (34,023) | $ (24,731) |
| **Income (loss) available to common stockholders basic (Note 11):** | | | |
| Income (loss) from continuing operations | $ 11,311 | $ (33,823) | $ (24,789) |
| Net income (loss) | $ 11,311 | $ (45,971) | $ (24,731) |
| **Income (loss) available to common stockholders diluted (Note 11):** | | | |
| Income (loss) from continuing operations | $ 11,491 | $ (33,823) | $ (24,789) |
| Net income (loss) | $ 11,491 | $ (45,971) | $ (24,731) |
| **Income (loss) per common share basic (Notes 2(k) and 11):** | | | |
| Income (loss) from continuing operations | $ 0.72 | $ (3.40) | $ (3.89) |
| Net income (loss) | $ 0.72 | $ (4.62) | $ (3.88) |

| | 2003 | 2002 | 2001 |
|---|---|---|---|
| **Income (loss) per common share diluted (Notes 2(k) and 11):** | | | |
| Income (loss) from continuing operations | $ 0.64 | $ (3.40) | $ (3.89) |
| Net income (loss) | $ 0.64 | $ (4.62) | $ (3.88) |
| **Weighted average shares basic** | 15,711 | 9,940 | 6,368 |
| **Weighted average shares diluted** | 17,834 | 9,940 | 6,368 |

(1) Stock-based compensation expense by statement of operations classifications is as follows:

| | | | |
|---|---|---|---|
| Research and development | $ 87 | $ 37 | $ 9,346 |
| Sales and marketing | | 26 | |
| General and administrative | 360 | 10,562 | 1,095 |
| Total stock-based compensation | $ 447 | $ 10,625 | $ 10,441 |

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



**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**

**CONSOLIDATED BALANCE SHEETS**

**(in thousands, except per share amounts)**

| | December 31, | |
|---|---|---|
| | 2003 | 2002 |
| | | (restated) |
| **ASSETS** | | |
| **Current assets:** | | |
| Cash and cash equivalents | $ 24,622 | $ 30,668 |
| Accounts receivable, net of allowances of $7,492 and $7,538 at December 31, 2003 and 2002, respectively | 55,418 | 36,904 |
| Inventories | 47,043 | 37,043 |
| Deferred tax assets | 1,178 | 2,137 |
| Prepaid expenses and other current assets | 10,599 | 6,456 |
| **Total current assets** | 138,860 | 113,208 |
| Property, plant and equipment, net | 56,999 | 46,029 |
| Goodwill | 233,792 | 108,915 |
| Trademarks and trade names with indefinite lives | 38,119 | 31,719 |
| Core technology and patents, net | 36,423 | 25,805 |
| Other intangible assets, net | 27,743 | 22,374 |
| Deferred financing costs, net, and other non-current assets | 7,457 | 4,908 |
| Deferred tax assets | 4,075 | 4,297 |

| | December 31, | |
|---|---|---|
| **Total assets** | $ 543,468 | $ 357,255 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| **Current liabilities:** | | |
| Current portion of long-term debt | $ 14,055 | $ 17,200 |
| Current portion of capital lease obligations | 457 | 642 |
| Accounts payable | 38,006 | 29,229 |
| Accrued expenses and other current liabilities | 41,122 | 38,452 |
| **Total current liabilities** | 93,640 | 85,523 |
| **Long-term liabilities:** | | |
| Long-term debt | 159,838 | 84,533 |
| Capital lease obligations | 1,831 | 2,238 |
| Deferred tax liabilities | 9,118 | 9,365 |
| Other long-term liabilities | 3,307 | 3,936 |
| **Total long-term liabilities** | 174,094 | 100,072 |
| **Commitments and contingencies (Notes 8 and 10)** | | |
| **Series A redeemable convertible preferred stock, $0.001 par value:** | | |
| Authorized 2,667 shares | | |
| Issued 2,527 shares at December 31, 2003 and 2002 | | |
| Outstanding 208 and 323 shares at December 31, 2003 and 2002, respectively | 6,185 | 9,051 |
| **Stockholders' equity:** | | |
| Preferred stock, $0.001 par value: | | |
| Authorized 2,333 shares, none issued | | |
| Common stock, $0.001 par value: | | |
| Authorized 50,000 shares | | |
| Issued and outstanding 19,640 and 14,907 shares at December 31, 2003 and 2002, respectively | 20 | 15 |
| Additional paid-in capital | 341,703 | 251,457 |
| Notes receivable from stockholders | (14,691) | (14,691) |
| Deferred compensation | | (48) |
| Accumulated deficit | (69,296) | (80,608) |
| Accumulated other comprehensive income | 11,813 | 6,484 |
| **Total stockholders' equity** | 269,549 | 162,609 |
| **Total liabilities and stockholders' equity** | $ 543,468 | $ 357,255 |

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

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE INCOME (LOSS)**

**(in thousands, except per share amounts)**

| | Common Stock | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Number of Shares | $0.001 Par Value | Additional Paid-in Capital | Notes Receivable from Stockholders | Deferred Compensation | Accumulated Deficit | Accumulated Other Comprehensive Income | Total Stockholders Equity | Comprehensive Income (Loss) |
| BALANCE, DECEMBER 31, 2000 | 5,828 | $ 6 | $ 54,839 | $ | $ | $ (13,799) | $ 766 | $ 41,812 | |
| Common stock issued by IMT effected by exchange ratio and related stock split (Note 1) | 757 | 1 | (1) | | | | | | $ |
| Capital contribution from IMT related to income taxes for Inverness Medical, Inc | | | 987 | | | | | 987 | |
| Capital contribution from IMT in connection with split-off (Note 1) | | | 46,712 | | | | | 46,712 | |
| Exercise of common stock options and warrants | 279 | | 568 | | | | | 568 | |
| Issuance of stock for notes receivable | 1,818 | 2 | 14,690 | (14,691) | | | | 1 | |
| Deferred compensation (Note 12(c)) | | | 20,586 | | (20,586) | | | | |
| Amortization of deferred compensation expense (Note 12(c)) | | | | | 10,441 | | | 10,441 | |
| Beneficial conversion feature on issuance of series A redeemable convertible preferred stock, net of issuance costs of $52 (Note 12(b)) | | | 7,928 | | | | | 7,928 | |
| Amortization of beneficial conversion feature related to series A redeemable convertible preferred stock (Note 12(b)) | | | | | | (25) | | (25) | |
| Original issue discount and beneficial conversion feature on issuance of convertible debt (Notes 6(f) and (g)) | | | 5,020 | | | | | 5,020 | |
| Changes in cumulative translation adjustment | | | | | | | 901 | 901 | 901 |
| Net loss | | | (3,918) | | | (20,813) | | (24,731) | (24,731) |
| Total comprehensive loss | | | | | | | | | $ (23,830) |
| BALANCE, DECEMBER 31, 2001 | 8,682 | $ 9 | $ 147,411 | $ (14,691) | $ (10,145) | $ (34,637) | $ 1,667 | $ 89,614 | |

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



**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE INCOME (LOSS) (Continued)**
**(in thousands, except per share amounts)**

| | Common Stock |
|---|---|

| | Common Stock | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Number of Shares | $0.001 Par Value | Additional Paid-in Capital | Notes Receivable from Stockholders | Deferred Compensation | Accumulated Deficit | Accumulated Other Comprehensive Income | Total Stockholders Equity | Comprehensive Income (Loss) |
| | | | | | | (restated) | | (restated) | (restated) |
| BALANCE, DECEMBER 31, 2001 | 8,682 | $ 9 | $ 147,411 | $ (14,691) | $ (10,145) | $ (34,637) | $ 1,667 | $ 89,614 | |
| Issuance of common stock, net of issuance costs of $2,521 | 1,600 | 2 | 34,277 | | | | (restated) | 34,279 | $ |
| Exercise of common stock options and warrants | 217 | | 1,043 | | | | | 1,043 | |
| Conversion of series A redeemable convertible preferred stock to common stock | 4,408 | 4 | 67,877 | | | (8,811) | | 59,070 | |
| Excess of redemption value related to issuance of series A redeemable convertible preferred stock, net of issuance costs of $183 (Note 12(b)) | | | 4,610 | | | | | 4,610 | |
| Beneficial conversion feature on issuance of series A redeemable convertible preferred stock (Note 12(b)) | | | 2,867 | | | | | 2,867 | |
| Dividends related to series A redeemable convertible preferred stock (Note 12(b)) | | | | | | (326) | | (326) | |
| Redemption interest and amortization of beneficial conversion feature related to series A redeemable convertible preferred stock (Note 12(b)) | | | | | | (2,811) | | (2,811) | |
| Beneficial conversion feature related to early extinguishment of convertible debt (Note 6(g)) | | | (9,600) | | | | | (9,600) | |
| Warrants issued with subordinated debt (Note 6(b)) | | | 1,502 | | | | | 1,502 | |
| Fair value of assumed and issued fully-vested stock options related to acquisition of IVC Industries, Inc. (Note 4(e)) | | | 1,299 | | | | | 1,299 | |
| Stock-based compensation related to grants of common stock options and warrants to non-employees | | | 477 | | | | | 477 | |
| Deferred compensation related to grants of common stock options to non-employees | | | 51 | | (51) | | | | |
| Amortization of deferred compensation (Note 12(c)) | | | | | 10,148 | | | 10,148 | |
| Changes in net parent company investment | | | (357) | | | | | (357) | |
| Changes in cumulative translation adjustment | | | | | | | 4,817 | 4,817 | 4,817 |
| Net loss | | | | | | (34,023) | | (34,023) | (34,023) |
| Total comprehensive loss | | | | | | | | | $ (29,206) |
| BALANCE, DECEMBER 31, 2002 | 14,907 | $ 15 | $ 251,457 | $ (14,691) | $ (48) | $ (80,608) | $ 6,484 | $ 162,609 | |

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

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY AND COMPREHENSIVE INCOME (LOSS) (Continued)**
**(in thousands, except per share amounts)**

| | Common Stock | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Number of Shares | $0.001 Par Value | Additional Paid-in Capital | Notes Receivable from Stockholders | Deferred Compensation | Accumulated Deficit | Accumulated Other Comprehensive Income | Total Stockholders Equity | Comprehensive Income (Loss) |
| | | | | | | (restated) | (restated) | (restated) | (restated) |
| BALANCE, DECEMBER 31, 2002 | 14,907 | $ 15 | $ 251,457 | $ (14,691) | $ (48) | $ (80,608) | $ 6,484 | $ 162,609 | |
| Issuance of common stock in connection with acquisitions and purchase of intellectual property, net of issuance costs of $50 | 4,068 | 4 | 80,220 | | | | | 80,224 | $ |
| Exercise of common stock options and warrants | 435 | 1 | 4,051 | | | | | 4,052 | |
| Conversion of series A redeemable convertible preferred stock to common stock (Note 12(b)) | 230 | | 3,824 | | | (362) | | 3,462 | |
| Dividends related to series A redeemable convertible preferred stock (Note 12(b)) | | | | | | (33) | | (33) | |
| Redemption interest and amortization of beneficial conversion feature related to series A redeemable convertible preferred stock (Note 12(b)) | | | | | | (562) | | (562) | |
| Fair value of assumed and fully-vested stock options and warrants related to acquisition of Ostex International, Inc. (Note 4(c)) | | | 1,752 | | | | | 1,752 | |
| Stock-based compensation related to grants of common stock options | | | 399 | | | | | 399 | |
| Amortization of deferred compensation | | | | | 48 | | | 48 | |
| Other | | | | | | | 136 | 136 | 136 |
| Pension liability adjustment (Note 8(b)) | | | | | | | (434) | (434) | (434) |
| Changes in cumulative translation adjustment | | | | | | | 5,627 | 5,627 | 5,627 |
| Net income | | | | | | 12,269 | | 12,269 | 12,269 |
| Total comprehensive income | | | | | | | | | $ 17,598 |
| BALANCE, DECEMBER 31, 2003 | 19,640 | $ 20 | $ 341,703 | $ (14,691) | $ | $ (69,296) | $ 11,813 | $ 269,549 | |

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



**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

**(in thousands)**

| | 2003 | 2002 | 2001 |
|---|---|---|---|
| | (restated) | (restated) | |
| **Cash Flows from Operating Activities:** | | | |
| Net income (loss) | $ 12,269 | $ (34,023) | $ (24,731) |
| Income from discontinued operations | | | (58) |
| Net income (loss), excluding discontinued operations | 12,269 | (34,023) | (24,789) |
| Adjustments to reconcile net income (loss) 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 | 1,565 | 7,499 | 839 |
| Noncash (income) expense related to interest rate swap agreement | (528) | 1,223 | |
| Noncash stock-based compensation expense | 447 | 10,625 | 10,441 |
| Charge for in-process research and development | | | 6,980 |
| Noncash beneficial conversion feature related to early extinguishment of convertible debt | | (9,600) | |
| Noncash charge related to asset impairment and cumulative effect of a change in accounting principle | | 24,830 | |
| Depreciation and amortization | 15,585 | 10,308 | 3,241 |
| Deferred income taxes | (1,047) | 26 | 419 |
| Other noncash items | | 354 | 546 |
| Capital contribution from Inverness Medical Technology, Inc. related to income taxes for Inverness Medical, Inc. | | | 987 |
| Changes in assets and liabilities, net of acquisitions: | | | |
| Accounts receivable, net | (9,592) | 1,227 | 1,756 |
| Inventory | (2,054) | (2,090) | (223) |
| Prepaid expenses and other current assets | (4,102) | 468 | (1,817) |
| Accounts payable | 6,715 | 8,847 | (736) |
| Accrued expenses and other current liabilities | (9,457) | (10,558) | 15,095 |
| Due to Inverness Medical Technology, Inc. and affiliates | | | 2,649 |
| **Net cash provided by continuing operations** | 9,801 | 9,136 | 15,388 |
| **Net cash used in discontinued operations** | | | (1,170) |
| **Cash Flows from Investing Activities:** | | | |
| Purchases of property, plant and equipment | (11,135) | (6,077) | (3,594) |
| Proceeds from sale of property, plant and equipment | 152 | 1,545 | 141 |
| Cash paid for purchase of assets from Abbott Laboratories | (55,947) | | |
| Cash paid for purchase of Applied Biotech, Inc., net of cash acquired | (14,042) | | |
| Cash paid for purchase of Ostex International, Inc., net of cash acquired | (1,903) | | |
| Cash paid for purchase of the Wampole Division of MedPointe Inc. | (1,460) | (70,608) | |
| Cash paid for purchase of IVC Industries, Inc., net of cash acquired | (535) | (7,112) | |
| Cash paid for purchase of Unipath business, net of cash acquired | (649) | (2,832) | (146,154) |
| Cash paid for purchase of other businesses and intellectual property | (4,007) | | |
| Loan to Ostex International, Inc. | | (1,000) | |
| Decrease (increase) in other assets | 396 | (560) | 129 |
| **Net cash used in investing activities** | (89,130) | (86,644) | (149,478) |
| **Cash Flows from Financing Activities:** | | | |
| Cash paid for financing costs | (4,533) | (3,975) | (2,196) |
| Proceeds from issuance of common stock, net of issuance costs | 4,003 | 35,322 | 568 |
| Proceeds from issuance of preferred stock, net of issuance costs | | 20,567 | 59,798 |

| | 2003 | 2002 | 2001 |
|---|---|---|---|
| Net proceeds received under revolving line of credit | 19,331 | 2,649 | |
| Proceeds from borrowings under notes payable | 57,621 | 84,421 | 82,552 |
| Repayments of notes payable | (5,785) | (82,240) | (4,307) |
| Principal payments of capital lease obligations | (651) | (494) | |
| Contribution from Inverness Medical Technology, Inc. | | | 47,659 |
| **Net cash provided by financing activities** | 69,986 | 56,250 | 184,074 |
| Foreign exchange effect on cash and cash equivalents | 3,297 | (98) | 138 |
| **Net (decrease) increase in cash and cash equivalents** | (6,046) | (21,356) | 48,952 |
| **Cash and cash equivalents, beginning of year** | 30,668 | 52,024 | 3,072 |
| **Cash and cash equivalents, end of year** | $ 24,622 | $ 30,668 | $ 52,024 |

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



**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)**

**(in thousands)**

| | 2003 | 2002 | 2001 |
|---|---|---|---|
| **Supplemental Disclosure of Cash Flow Information:** | | | |
| Interest paid | $ 9,091 | $ 4,519 | $ 895 |
| Taxes paid | $ 1,447 | $ 2,728 | $ 45 |
| **Supplemental Disclosure of Noncash Activities:** | | | |
| Net assets of discontinued operations (Note 16(d)) | $ | $ | $ (19,400) |
| Long-term debt discharged as part of split-off from Inverness Medical Technology, Inc. (Note 1) | $ | $ | $ 8,084 |
| Forgiveness of amounts due to Inverness Medical Technology, Inc. and affiliates, net (Note 16(b)) | $ | $ | $ 10,369 |
| On September 30, 2003, the Company acquired certain assets from Abbott Laboratories (Note 4 (a)) | | | |
| Property, plant and equipment | $ 536 | $ | $ |
| Intangible assets | 94,451 | | |
| Accrued acquisition costs | (1,540) | | |
| Cash paid for purchase of certain assets from Abbott Laboratories | (55,947) | | |
| Fair value of common stock issued | $ 37,500 | $ | $ |

| | 2003 | 2002 | 2001 |
|---|---|---|---|
| On August 27, 2003, the Company acquired Applied Biotech, Inc. (Note 4 (b)) | | | |
| Accounts receivable | $ 6,368 | $ | $ |
| Inventory | 6,056 | | |
| Property, plant and equipment | 5,352 | | |
| Intangible assets | 15,615 | | |
| Other assets | 117 | | |
| Accounts payable and accrued expenses | (4,669) | | |
| Accrued acquisition costs | (530) | | |
| Cash paid for purchase of Applied Biotech, Inc., net of cash acquired | (14,042) | | |
| Fair value of common stock issued | $ 14,267 | $ | $ |
| On June 30, 2003, the Company acquired Ostex International, Inc. (Note 4(c)) | | | |
| Accounts receivable | $ 1,264 | $ | $ |
| Inventory | 506 | | |
| Property, plant and equipment | 629 | | |
| Intangible assets | 31,468 | | |
| Other assets | 177 | | |
| Accounts payable and accrued expenses | (1,891) | | |
| Long-term debt | (2,875) | | |
| Accrued acquisition costs | (2,086) | | |
| Cash paid for purchase of Ostex International, Inc., net of cash acquired | (1,903) | | |
| | $ 25,289 | $ | $ |
| Fair value of common stock issued | $ 23,537 | $ | $ |
| Fair value of assumed and issued fully-vested stock options and warrants | 1,752 | | |
| Total fair value of equity instruments issued | $ 25,289 | $ | $ |

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



**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**

**CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)**

**(in thousands)**

| | 2003 | 2002 | 2001 |
|---|---|---|---|
| On September 20, 2002, the Company acquired the Wampole Division from MedPointe Inc. (Note 4(d)) | | | |
| Accounts receivable | $ (451) | $ 8,737 | $ |
| Inventory | (75) | 4,924 | |
| Other current assets | 1 | 967 | |
| Property and equipment | 156 | 2,061 | |

| | 2003 | 2002 | 2001 |
|---|---|---|---|
| Intangible assets | 1,138 | 56,301 | |
| Accounts payable and accrued expenses | (201) | (1,490) | |
| Accrued acquisition costs | 892 | (892) | |
| Cash paid for purchase of the Wampole Division | (1,460) | (70,608) | |
| | $ | $ | $ |
| On March 19, 2002, the Company acquired IVC Industries, Inc. (Note 4(e)) | | | |
| Accounts receivable | $ | $ 4,716 | $ |
| Inventory | | 9,832 | |
| Property and equipment | | 23,016 | |
| Other assets | | 1,755 | |
| Accounts payable and accrued expenses | | (12,495) | |
| Other accrued acquisition costs | 535 | (1,054) | |
| Long-term debt | | (17,359) | |
| Cash paid for purchase of IVC Industries, Inc., net of cash acquired | (535) | (7,112) | |
| Fair value of assumed and issued fully-vested stock options | $ | $ 1,299 | $ |
| On December 20, 2001, the Company acquired the Unipath business (Note 4(f)) | | | |
| Accounts receivable | $ | $ | $ 15,960 |
| Inventory | 39 | | 13,067 |
| Other current assets | | | 2,369 |
| Property and equipment | | | 15,182 |
| Intangible assets | (624) | 484 | 134,523 |
| Unfunded pension liability | | 1,052 | (3,685) |
| Other accrued acquisition costs | 822 | 1,296 | (3,266) |
| Other liabilities | 412 | | (27,996) |
| Cash paid for purchase of Unipath business, net of cash acquired | (649) | (2,832) | (146,154) |
| | $ | $ | $ |
| During 2003, the Company acquired other businesses and intellectual property | | | |
| Accounts receivable | $ 116 | $ | $ |
| Property, plant and equipment | 616 | | |
| Intangible asset | 10,445 | | |
| Other assets | 39 | | |
| Accounts payable and accrued expenses | (356) | | |
| Deferred tax liabilities | (1,884) | | |
| Cash paid for purchase of other businesses and intellectual property | (4,007) | | |
| Fair value of common stock issued | $ 4,969 | $ | $ |
| Dividends, interest and amortization of beneficial conversion feature related to preferred stock (Notes 11 and 12(b)) | $ 958 | $ 11,948 | $ |
| Conversion of preferred stock to common stock (Note 12(b)) | $ 3,824 | $ 67,881 | $ |

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

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS**

**(in thousands, except per share amounts)**

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

Inverness Medical Innovations, Inc. and subsidiaries (the "Company") develop, manufacture and market diagnostic products for the over-the-counter pregnancy and fertility/ovulation test market and the professional rapid diagnostic test market worldwide. In addition, the Company manufactures a variety of vitamins and nutritional supplements that it markets under its brands and those of private label retailers in the consumer market primarily in the United States.

The Company's business is organized into two reportable segments, consumer products and professional diagnostics. The consumer products segment includes the Company's over-the-counter pregnancy and fertility/ovulation tests and vitamins and nutritional supplements. The professional diagnostic products segment includes an array of innovative rapid diagnostic test products and other in vitro diagnostic tests marketed to medical professionals and laboratories for detection of infectiouse diseases, drugs of abuse and pregnancy.

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 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 $41,400 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 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 reflect interest expense on amounts due to entities not included in the Company's consolidated financial statements (primarily to IMT) (Note 16(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 and 118, 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 $645, 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 $1,173, 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 2003 and 2002, the Company recognized stock-based compensation expense related to certain of the IMT employees who became Company employees in the amount of $2 and $121, respectively, 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. During 2003, the Company acquired certain assets from Abbott Laboratories ("Abbott") on September 30, 2003 (the "Abbott business"), Applied Biotech, Inc. and subsidiary ("ABI") from Apogent Technologies Inc. on August 27, 2003 and Ostex International, Inc. ("Ostex") on June 30, 2003 (Note 4). The assets acquired from Abbott relate to consumer diagnostic pregnancy tests and various professional rapid diagnostic product lines, as well as certain transferred and licensed intellectual property related to these products. ABI is a developer, manufacturer and distributor of consumer diagnostic and professional diagnostic products in the areas of women's health, infectious disease and drugs of abuse testing. Ostex develops and commercializes osteoporosis diagnostics products and holds intellectual property rights in the field of osteoporosis diagnostics. In addition, the Company acquired a small research and development facility, Scandinavian Micro Biodevices A/S ("SMB"), on November 18, 2003.

Acquisitions that occurred during 2002 and 2001 include the Company's acquisition of the Wampole Division of MedPointe Inc. ("Wampole") on September 20, 2002, IVC Industries, Inc. (d/b/a Inverness Medical Nutritionals Group or "IMN") 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 and professional medical diagnostic products. IMN manufactures and distributes vitamins and nutritional supplements. The Unipath business develops, manufactures and distributes women's health and professional diagnostics products.

The results of these acquisitions 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 of America, 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.

*(b) Foreign Currencies*

The Company follows the provisions of SFAS No. 52, *Foreign Currency Translation*. In general, the functional currencies of the Company's foreign subsidiaries are the local currencies. For purpose of consolidating the financial statements of the Company's foreign subsidiaries, all assets and liabilities of the foreign subsidiaries are translated into U.S. dollars using the exchange rate at each balance sheet date while the stockholders' equity accounts are translated at historical exchange rates. Translation gains and losses that result from the conversion of the balance sheets of the foreign subsidiaries into U.S. dollars are recorded to cumulative translation adjustment which is a component of accumulated other comprehensive income within stockholders' equity (Note 13).

The income and expense accounts of the Company's foreign subsidiaries are translated using the average rates of exchange during each reporting period. Net realized and unrealized foreign currency

exchange transaction gains of $5 and losses of $1,618 and $727 during 2003, 2002 and 2001, 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, 2003 and 2002.

*(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), buildings (20-39 years), leasehold improvements (lesser of remaining term of lease or estimated useful life of asset), computer software and equipment (3-6 years) and furniture and fixtures (3-10 years). Depreciation and amortization expense related to property, plant and equipment amounted to $10,116, $6,364 and $1,864 in 2003, 2002 and 2001, respectively.

*(f) Goodwill and Other Intangible Assets*

The following is a summary of goodwill and other intangible assets as of December 31, 2003:

| | Gross Carrying Amount | Accumulated Amortization | Useful Life |
|---|---|---|---|
| **Amortized intangible assets:** | | | |
| Core technology and patents | $ 42,888 | $ 6,465 | 10-15 years |
| Other intangible assets | | | |
| Supplier relationships | 11,020 | 1,410 | 10 years |
| Trademarks and trade name | 9,978 | 4,600 | 5-25 years |
| License agreements | 8,903 | 2,585 | 7 years |
| Other | 6,596 | 159 | 15 years |
| | $ 79,385 | $ 15,219 | |
| **Intangible assets with indefinite lives:** | | | |
| Goodwill | $ 233,792 | | |
| Trademarks and trade names | 38,119 | | |
| | $ 271,911 | | |

The Company amortizes intangible assets with finite lives using the straight-line method over the above estimated useful lives of the respective intangible asset. The Company believes that the straight-

line method is appropriate, as it approximates the pattern in which economic benefits are consumed. Amortization expense of intangible assets, which amounted to $5,469, $3,944 and $1,377 in 2003, 2002 and 2001, respectively, is included in cost of sales and research and development 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, 2003:

| | |
|---|---|
| 2004 | $ 6,456 |
| 2005 | 6,449 |
| 2006 | 6,449 |
| 2007 | 6,430 |
| 2008 | 6,290 |

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 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 as a result of an independent appraisal of its nutritional supplement reporting unit (Note 5). Based on an impairment review on December 31, 2003, the Company does not believe that goodwill related to its consumer products and professional diagnostic products business segments was impaired. The values assigned to the trade names that were acquired as part of the Abbott business and Wampole acquisitions (Notes 4(a) and (d)) and trademarks that were acquired as part of the Unipath business acquisition (Note 4(f)), have been assigned indefinite lives and therefore, in accordance with SFAS No. 142 are not being amortized.

The Company allocates goodwill by segment based on the percentage of estimated future revenues generated for the respective segment as of the acquisition date. Goodwill allocated by business segment is as follows:

| | Consumer Products | Professional Diagnostic Products | Total |
|---|---|---|---|
| Goodwill, at December 31, 2001 | $ 78,317 | $ 7,058 | $ 85,375 |
| Acquisitions | 200 | 35,362 | 35,562 |
| Impairment charge (Note 5) | (12,148) | | (12,148) |
| Other | 124 | 2 | 126 |
| Goodwill, at December 31, 2002 | 66,493 | 42,422 | 108,915 |
| Acquisitions (Note 4) | 25,387 | 98,971 | 124,358 |
| Other | (589) | 1,108 | 519 |
| Goodwill, at December 31, 2003 | $ 91,291 | $ 142,501 | $ 233,792 |

*(g) Impairment of Other Long-Lived Tangible 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 tangible and intangible assets to determine whether there are any impairment losses. If indicators of impairment were present with respect to long-lived tangible 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 $12,682 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 tangible and intangible assets were realizable as of December 31, 2003.

*(h) Income Taxes*

The Company follows the provisions of SFAS No. 109 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. The provisions of SFAS No. 109 also require the recognition of future tax benefits such as net operating loss carry-forwards, to the extent that the realization of such benefits is more likely than not. To the extent that it is not likely that the Company will benefit from such benefits, the Company must establish a valuation allowance against the related deferred tax assets (Note 14).

*(i) Revenue Recognition*

The majority of the Company's revenues are derived from product sales. The Company generally does not enter into arrangements with multiple element deliverables. The Company recognizes revenue when the following four basic criteria have been met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services rendered; (3) the fee is fixed and determinable; and (4) collection is reasonably assured. The Company recognizes revenue upon title transfer of the products to third-party customers, less a reserve for estimated product returns and allowances.

To a lesser extent, the Company also receives 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 generally recognized upon receipt of the license or royalty payments unless the Company is able to reasonably estimate the fees as they are earned. License and royalty fees that are determinable prior to the receipt thereof are recognized in the period they are earned.

*(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 consolidated 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 related interpretations. The Company has elected to use the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, and as amended by 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 date for awards under the stock option plans consistent with the method prescribed by SFAS No. 123, the Company's net income (loss) would have been decreased (increased) to the pro forma amounts indicated as follows:

| | 2003 | 2002 | 2001 |
|---|---|---|---|
| | (restated) | (restated) | |
| Net income (loss) as reported | $ 12,269 | $ (34,023) | $ (24,731) |
| Stock-based employee compensation as reported (a) | 397 | 10,268 | 9,796 |
| Pro forma stock-based employee compensation | (6,161) | (18,920) | (16,015) |
| Net income (loss) pro forma | $ 6,505 | $ (42,675) | $ (30,950) |
| **Income (loss) per common share basic** | | | |
| Net income (loss) as reported | $ 0.72 | $ (4.62) | $ (3.88) |
| Stock-based employee compensation as reported | 0.02 | 1.03 | 1.54 |
| Pro forma stock-based employee compensation | (0.39) | (1.90) | (2.52) |
| Net income (loss) per share pro forma | $ 0.35 | $ (5.49) | $ (4.86) |
| **Income (loss) per common share diluted** | | | |
| Net income (loss) as reported | $ 0.64 | $ (4.62) | $ (3.88) |
| Stock-based employee compensation as reported | 0.02 | 1.03 | 1.54 |
| Pro forma stock-based employee compensation | (0.34) | (1.90) | (2.52) |
| Net income (loss) per share pro forma | $ 0.32 | $ (5.49) | $ (4.86) |

(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 and options granted in lieu of cash compensation.

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, 2003 were as follows:

| | 2003 | 2002 | 2001 |
|---|---|---|---|
| Risk-free interest rate | 2.33-3.49% | 2.6-4.9% | 4.3-4.8% |
| Expected dividend yield | | | |
| Expected lives | 5 years | 5 years | 0.3-7 years |
| Expected volatility | 55% | 58% | 54-82% |

The weighted average fair value under the Black-Scholes option pricing model of options granted to employees during 2003, 2002 and 2001 was $9.34, $9.19 and $10.35, respectively.

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

Net income (loss) 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).

*(l) Other Operating Expenses*

The Company expenses advertising costs as incurred. In 2003, 2002 and 2001, advertising costs amounted to $18,594, $14,306 and $354, respectively, and are included in sales and marketing expenses in the accompanying consolidated statements of operations.

Shipping and handling costs are included in cost of sales in the accompanying consolidated statements of operations. Additionally, to the extent that the Company charges its customers for shipping and handling costs, these costs are recorded as product revenues.

*(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.

There were no accounts receivable balances outstanding at December 31, 2003, that were in excess of 10% of the gross accounts receivable balance on that date. 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. During 2003 and 2001, the Company had one customer that represented 11% and 14%, respectively, of its net revenues. There were no customers during 2002 that represented more than 10% of the Company's net revenues.

The Company relies on a number of third parties to manufacture certain of its products. If any of the Company's third party manufacturers cannot or will not manufacture the Company's products in

the required volumes, on a cost-effective basis, in a timely manner, or at all, the Company will have to secure additional manufacturing capacity. Any interruption or delay in manufacturing could have a material adverse effect on the Company's business and operating results.

In February 2002, the Company entered into an interest rate swap agreement which was intended to protect it from interest rate fluctuations related to a portion of its senior long-term debt. Other than this interest rate swap agreement, the Company had no significant other concentration of credit risks such as foreign exchange contracts, option contracts or other foreign hedging arrangements at December 31, 2003 and 2002. The Company had no off-balance sheet arrangements as of December 31, 2003. See Note 15 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, 2003 and 2002 consisted of cash equivalents, accounts receivable and debt. In addition, the Company also has an interest rate swap agreement. The estimated fair value of these financial instruments approximates their carrying values at December 31, 2003 and 2002. The estimated fair values have been determined through information obtained from market sources. Additionally, the Company's subsidiary in England enters into short-term 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, 2003, 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, including SFAS No. 149, *Amendment of Statement 133 on Derivative Instruments and Hedging Activities*.

*(o) Recent Accounting Pronouncements*

In November 2002, the Emerging Issues Task Force ("EITF") reached consensus on Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*. Revenue arrangements with multiple deliverables include arrangements which provide for the delivery or performance of multiple products, services and/or rights to use assets where performance may occur at different points in time or over different periods of time. EITF Issue No. 00-21 is effective for revenue arrangements entered into in fiscal periods beginning after June 15, 2003. The adoption of the guidance under this consensus did not have an impact on the Company's financial position, results of operations or cash flows.

In April 2003, the FASB issued SFAS No. 149 which amends and clarifies financial accounting and reporting for derivative instruments, including certain derivative instruments embedded in other contracts, and for hedging activities under SFAS No. 133. In particular, SFAS No. 149 clarifies under what circumstances a contract with an initial net investment meets the characteristic of a derivative discussed in SFAS No. 133, clarifies when a derivative contains a financing component, amends the definition of an underlying (as initially defined in SFAS No. 133) to conform it to language used in FIN No. 45, *Guarantor's Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others*, and amends certain other existing pronouncements. SFAS No. 149 is effective for all contracts entered into or modified after June 30, 2003, subject to certain exceptions.

The adoption of this statement did not have an impact on the Company's financial position, results of operations, or cash flows.

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

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

In December 2003, the Securities and Exchange Commission ("SEC") published SAB No. 104, *Revenue Recognition*. SAB No. 104 was effective upon issuance and supersedes SAB No. 101, *Revenue Recognition in Financial Statements*, and rescinds the accounting guidance contained in SAB No. 101 related to multiple-element revenue arrangements that was superseded by EITF Issue No. 00-21. Accordingly, SAB No. 104 rescinds portions of the interpretive guidance included in Topic 13 of the codification of staff accounting bulletins. While the wording of SAB No. 104 has changed to reflect the guidance of EITF 00-21, the revenue recognition principles of SAB No. 101 have remained largely unchanged. The adoption of SAB No. 104 did not have a material effect on the Company's financial position, results of operations, or cash flows.

*(p) Reclassifications*

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

*(q) Restatements of 2003 and 2002 Financial Statements*

The Company restated its previously issued consolidated financial statements as of and for the year ended December 31, 2002 to reverse a realized foreign exchange gain of $2,593 related to the repayment of a portion of a long-term intercompany loan that had previously been reported in other income (expense), net, and to instead reflect the change in value of the intercompany loan prior to repayment as a component of accumulated other comprehensive income. In connection with this restatement, the Company also restated its previously issued consolidated financial statements for the quarterly impacts of certain adjustments related to sales cut-off and sales incentive allowances, the effects of which on operating results had previously been corrected in the periods in which they had been identified rather than in the periods to which they related.

The following lists the accounts in the consolidated statements of operations and balance sheets that were affected by the restatements discussed above, with comparisons of the restated amounts to previously reported amounts, and the effect of such restatements on gross profit, income (loss) from continuing operations, net income (loss) and earnings (loss) per share.

| | 2003 | |
|---|---|---|
| | **As restated** | **As reported** |
| Net product sales | $ 286,984 | $ 286,689 |
| Gross profit | 128,592 | 128,297 |
| Income (loss) from continuing operations | 12,269 | 11,974 |
| Net income (loss) | 12,269 | 11,974 |
| Income (loss) per common share basic: | | |
| Income (loss) from continuing operations | $ 0.72 | $ 0.70 |
| Net income (loss) | $ 0.72 | $ 0.70 |
| Income (loss) per common share diluted: | | |
| Income (loss) from continuing operations | $ 0.64 | $ 0.63 |
| Net income (loss) | $ 0.64 | $ 0.63 |

| | December 31, 2003 | |
|---|---|---|
| | **As restated** | **As reported** |
| Accumulated deficit | $ (69,296) | $ (66,703) |
| Accumulated other comprehensive income | 11,813 | 9,220 |

| | 2002 | |
|---|---|---|
| | As restated | As reported |
| Net product sales | $ 200,399 | $ 201,641 |
| Cost of sales | 114,653 | 115,600 |
| Gross profit | 92,151 | 92,446 |
| Other income (expense), net | 9,114 | 11,707 |
| Income (loss) from continuing operations | (21,875) | (18,987) |
| Net income (loss) | (34,023) | (31,135) |
| Income (loss) per common share basic: | | |
| Income (loss) from continuing operations | $ (3.40) | $ (3.11) |
| Net income (loss) | $ (4.62) | $ (4.33) |
| Income (loss) per common share diluted: | | |
| Income (loss) from continuing operations | $ (3.40) | $ (3.11) |
| Net income (loss) | $ (4.62) | $ (4.33) |

| | December 31, 2002 | |
|---|---|---|
| | As restated | As reported |
| Accounts receivable, net of allowances | $ 36,904 | $ 37,283 |
| Inventories | 37,043 | 37,155 |
| Accrued expenses and other current liabilities | 38,452 | 38,648 |
| Accumulated deficit | (80,608) | (77,720) |
| Accumulated other comprehensive income | 6,484 | 3,891 |

All applicable amounts relating to the aforementioned restatements have been reflected in these consolidated financial statements and notes hereto.

**(3) Other Balance Sheet Information**

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

| | December 31, | |
|---|---|---|
| | 2003 | 2002 |
| | | (restated) |
| **Inventory:** | | |
| Raw materials | $ 19,606 | $ 13,447 |
| Work-in-process | 12,631 | 7,076 |
| Finished goods | 14,806 | 16,520 |
| | $ 47,043 | $ 37,043 |
| **Property, plant and equipment:** | | |
| Machinery, laboratory equipment and tooling | $ 51,428 | $ 34,750 |
| Buildings | 8,919 | 8,726 |
| Leasehold improvements | 8,349 | 6,094 |
| Computer software and equipment | 5,505 | 4,741 |
| Furniture and fixtures | 2,714 | 2,120 |
| | 76,915 | 56,431 |
| Less Accumulated depreciation and amortization | 19,916 | 10,402 |
| | $ 56,999 | $ 46,029 |
| **Accrued expenses and other current liabilities:** | | |
| Compensation and compensation-related | $ 10,259 | $ 8,851 |
| Advertising and marketing | 9,146 | 9,299 |
| Professional fees | 6,518 | 5,688 |
| Royalty obligations | 4,810 | 1,116 |
| Other | 10,389 | 13,498 |
| | $ 41,122 | $ 38,452 |

**(4) Business Combinations**

*(a) Acquisition of the Abbott business*

On September 30, 2003, the Company acquired from Abbott certain assets related to Abbott's lines of consumer diagnostic pregnancy tests and professional rapid diagnostics for various testing needs, including strep throat, pregnancy and drugs of abuse (Note 1). The acquired assets also include certain transferred and licensed intellectual property related to these products. This acquisition compliments the Company's consumer and professional diagnostic product portfolios, as well as helps to establish a larger global presence in which to facilitate the introduction of new products.

The aggregate purchase price was $94,987, which consisted of $55,000 in cash, $37,500 in the form of 1,551 shares of the Company's common stock and direct acquisition costs of $2,487. The Company financed the cash portion of the purchase price by obtaining loans under its amended senior credit facility (Note 6(a)).

The aggregate purchase price was allocated to the assets acquired as follows:

| | | |
|---|---|---|
| Property, plant and equipment | $ | 536 |
| Goodwill | | 86,451 |
| Trade name Signify | | 6,400 |
| Trade name Fact plus | | 1,600 |
| | $ | 94,987 |

The fair value assigned to property, plant and equipment and trade names were based upon an independent appraisal.

The acquisition of the Abbott business is accounted for as a purchase under SFAS No. 141, *Business Combinations*. Accordingly, the operating results of the Abbott business have been included in the Company's consolidated statements of operations after the acquisition date as part of each of the Company's consumer diagnostic products and professional diagnostic products reporting units. The acquired goodwill, all of which is deductible for tax purposes over a period of 15 years, is allocated by business segment based on estimated future revenue of the acquired assets as follows: $23,385 to consumer products and $63,066 to professional diagnostic products. The Company has assigned an indefinite life to the Signify trade name and 5 years in useful life for the Fact plus trade name. The Signify and Fact plus trade names are included on the accompanying consolidated balance sheet as of December 31, 2003 in trademark and trade names with indefinite lives and other intangible assets, net, respectively.

Under the terms of the acquisition agreements, Abbott will provide transitional services for up to eighteen months for several of the acquired products and up to two years for others. The transitional services primarily include distributing the acquired products, but also include limited manufacturing.

*(b) Acquisition of ABI*

On August 27, 2003, the Company acquired ABI from Apogent Technologies Inc. ("Apogent") (Note 1). ABI is a developer, manufacturer and distributor of rapid diagnostic products in the areas of women's health, infectious disease and drugs of abuse testing. In the transaction, the Company also acquired ABI's wholly-owned subsidiary, Forefront Diagnostics, Inc. ("Forefront"). Forefront develops, manufactures and distributes rapid diagnostic products for drugs of abuse testing. These products broaden the Company's professional diagnostic product portfolio. ABI also provides the Company with additional manufacturing capabilities and new distribution channels for the Company's professional diagnostic products.

The preliminary aggregate purchase price of ABI was $28,840, which consisted of $13,400 in cash, 693 shares of the Company's common stock with an aggregate fair value of $14,267 and preliminary direct acquisition costs of $1,173. The fair value of the Company's common stock was determined based on the average market price of the Company's common stock over the periods just prior to and following the date of the merger agreement, pursuant to EITF Issue No. 99-12, *Determination of the Measurement Date for the Market Price of Acquirer Securities Issued in a Purchase Business Combination.* The Company financed the cash portion of the purchase price by obtaining a loan under its amended senior credit facility (Note 6(a)).



The aggregate purchase price is preliminary as the Company is working to settle a working capital adjustment with Apogent under the purchase agreement and management is in the process of finalizing a restructuring plan for the operations of ABI, both of which could result in adjustments to the aggregate purchase price. The following table summarizes the preliminary fair value of the assets acquired and liabilities assumed at the date of acquisition:

| | | |
|---|---|---|
| Cash and cash equivalents | $ | 1 |
| Accounts receivable | | 6,368 |
| Inventory | | 6,056 |
| Property, plant and equipment | | 5,352 |
| Goodwill | | 10,115 |
| Customer relationships | | 2,000 |

| | |
|---|---|
| Manufacturing know how | 3,500 |
| Other assets | 117 |
| Accounts payable and accrued expenses | (4,669) |
| | $ 28,840 |

The values assigned to the property, plant and equipment and intangible assets were based upon the results of an independent appraisal.

The acquisition of ABI is accounted for as a purchase under SFAS No. 141. Accordingly, the operating results of ABI have been included in the accompanying consolidated financial statements since the acquisition date as part of each of the Company's consumer diagnostic products and professional diagnostic products reporting units. The Company has allocated goodwill of $2,003 and $8,112 to the consumer products and professional diagnostic products business segments, respectively, based on estimated future revenue of the acquired businesses. Goodwill generated from this acquisition is not deductible for tax purposes. The Company estimates the useful lives of both intangible assets to be 15 years and has included them in other intangible assets, net, in the accompanying consolidated balance sheet at December 31, 2003. The weighted average amortization period for the acquired intangible assets with finite lives is estimated to be 15 years.

*(c) Acquisition of Ostex*

On June 30, 2003, the Company acquired Ostex through a merger transaction (Note 1). Ostex develops and commercializes osteoporosis diagnostic products. This acquisition also provides the Company with intellectual property rights in the field of osteoporosis diagnostics.

The preliminary aggregate purchase price of Ostex was $33,424, which consisted of 1,597 shares of the Company's common stock with an aggregate fair value of $23,537, the assumption of fully-vested stock options and warrants to purchase an aggregate of 303 shares of the Company's common stock, which options and warrants have an aggregate fair value of $1,752, estimated exit costs of $3,632, which primarily consists of severance and costs to vacate Ostex's manufacturing and administrative facilities in accordance with EITF Issue No. 95-3, *Recognition of Liabilities in Connection with a Purchase Business Combination*, direct acquisition costs of $1,628 and $2,875 in assumed debt. The fair value of the Company's common stock issued to acquire all of Ostex's outstanding common stock was determined



based on the average market price of the Company's common stock over the periods just prior to and following the date of the merger agreement, as amended, pursuant to EITF Issue No. 99-12. The fair value of the assumed fully-vested stock options and warrants was calculated using the Black-Scholes option pricing model.

As a result of the business combination with Ostex, the Company established a restructuring plan whereby it will exit the current facilities of Ostex in Seattle, Washington, and combine such activities with the Company's existing manufacturing and distribution facilities by mid-2004. The total number of employees to be terminated involuntarily will be 41, of which 30 remain to be terminated as of December 31, 2003. Total severance costs associated with employees to be terminated involuntarily are estimated to be $1,592, of which $1,132 has been paid as of December 31, 2003. The Company estimated costs to vacate the Ostex facilities to be approximately $100, none of which has been paid as of December 31, 2003. Additionally, the remaining costs to exit operations, primarily facilities lease commitments, are estimated at $1,940, of which $414 has been paid as of December 31, 2003. Total unpaid estimated exit costs amounted to $2,086 as of December 31, 2003.

Although the Company believes its plan and estimated exit costs to be reasonable, actual spending for exit activities may differ from current estimated exit costs, which might impact the final aggregate purchase price. The following table summarizes the preliminary estimated fair value of the assets acquired and liabilities assumed at the date of acquisition:

| | |
|---|---|
| Cash and cash equivalents | $ 1,271 |
| Accounts receivable | 1,264 |
| Inventory | 506 |
| Property, plant and equipment | 629 |
| Goodwill | 24,840 |
| Core technology | 5,532 |
| Customer relationships | 1,096 |
| Other assets | 177 |
| Accounts payable and accrued expenses | (1,891) |

| | |
|---|---|
| | $ 33,424 |

The values assigned to the property, plant and equipment and intangible assets were based upon the results of independent appraisals.

The acquisition of Ostex is accounted for as a purchase under SFAS No. 141. Accordingly, the results of Ostex 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. Goodwill generated from this acquisition is not deductible for tax purposes. The Company estimates the useful lives of both the core technology and customer relationships to be 15 years and includes them in core technology and patents, net, and other intangible assets, net, respectively, in the accompanying consolidated balance sheet at December 31, 2003. The weighted average amortization period for the acquired intangible assets with finite lives is estimated to be 15 years.



*(d) 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 $72,068, which consisted of $70,489 in cash and $1,579 in direct acquisition costs. The acquisition was funded by the issuance of $35,000 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 allocated to the acquired assets and assumed liabilities as follows:

| | |
|---|---|
| Accounts receivable | $ 8,286 |
| Inventory | 4,849 |
| Property, plant and equipment | 2,217 |
| Goodwill | 36,499 |
| Trade name | 6,020 |
| Patents | 3,900 |
| Supplier relationships | 11,020 |
| Other assets | 968 |
| Accounts payable and accrued expenses | (1,691) |
| | $ 72,068 |

The above allocation of the aggregate purchase price for Wampole to the acquired intangible assets is based upon an independent appraisal.

The acquisition of Wampole is accounted for as a purchase under SFAS No. 141. 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. 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. The trade name, patents, and supplier relationships are allocated respectively to trademarks and trade names with indefinite lives, core technology and patents, net, and other intangible assets, net, on the accompanying consolidated balance sheets as of December 31, 2003 and 2002.

*(e) Acquisition of IVC*

On March 19, 2002, the Company acquired IVC (now d/b/a IMN), a manufacturer and distributor of vitamins and nutritional supplements primarily in the United States (Note 1). With the addition of IMN, the Company consolidated certain of its vitamin and nutritional supplement manufacturing at IMN and discontinued most of its outsourced manufacturing arrangements. The aggregate purchase price of IMN was $27,300, which consisted of $5,619 in cash representing $2.50 for each outstanding share of IMN's common stock, fully-vested stock options to purchase an aggregate of 116 shares of the

Company's common stock, which options had an aggregate fair value of $1,299, calculated using the Black-Scholes option pricing model, $1,587 in costs to exit certain activities of IMN, primarily severance costs of involuntarily terminated employees in accordance with EITF Issue No. 95-3, $17,359 in assumed debt and $1,436 in direct acquisition costs. The acquisition was funded by the Company's existing cash. The aggregate purchase price for IMN was allocated to the acquired assets and assumed liabilities as follows:

| | | |
|---|---|---|
| Cash and cash equivalents | $ | 476 |
| Accounts receivable | | 4,716 |
| Inventory | | 9,832 |
| Property, plant and equipment | | 23,016 |
| Other assets | | 1,755 |
| Accounts payable and accrued expenses | | (12,495) |
| | $ | 27,300 |

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

Immediately after the close of the acquisition, the Company reorganized the business operations of IMN to improve efficiencies and eliminate redundant activities on a company-wide basis. The restructuring affected all cost centers within the organization, but most significantly responsibilities at the sales and executive levels, as such activities were combined with the Company's existing business operations. Also as part of the restructuring plan, the Company is in the process of relocating one of IMN's warehouses to a closer proximity of the manufacturing facility to improve efficiency. The warehouse relocation is expected to be completed by mid-2004. Of the $1,587 in total exit costs, which include severance costs of involuntarily terminated employees and costs to vacate the warehouse, $1,068 have been paid and $519 remain unpaid as of December 31, 2003. The total number of involuntarily terminated employees was 47, all of which have been terminated as of December 31, 2003.

*(f) 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 $158,446 consisted of $146,490 in cash, $4,159 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 $2,634 upon the assumption of the pension benefits of the acquired employees based in England (Note 8(b)) and $5,163 in direct acquisition costs. The acquisition was funded by the issuance of 1,995 shares of series A convertible redeemable preferred stock ("Series A Preferred Stock") with aggregate proceeds of $59,850 (Note 12(b)), $62,500 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 (Note 6(g)) and the Company's existing cash.

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

| | | |
|---|---|---|
| Cash and cash equivalents | $ | 5,030 |
| Accounts receivable | | 15,960 |
| Inventory | | 13,106 |
| Other current assets | | 2,369 |
| Property and equipment | | 15,182 |
| Goodwill and trademarks | | 98,428 |
| In-process research and development | | 6,980 |
| Core technology and patents | | 20,072 |
| License agreements | | 8,903 |
| Liabilities assumed | | (27,584) |

| | | |
|---|---|---|
| | $ | 158,446 |

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 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 acquired goodwill, the majority of which is not deductible for tax purposes, and trademarks are assigned indefinite lives. Goodwill of $65,703 and $7,026 has been allocated to the consumer products and professional diagnostic products business segments, respectively, based on estimated future revenue of the acquired Unipath business. 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 trademarks, core technology and patents, and license agreements are allocated to trademarks and trade names with indefinite lives, core technology and patents, net, and other intangible assets, net, respectively, in the accompanying consolidated balance sheets at December 31, 2003 and 2002.



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, 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. At the time of the Unipath business acquisition, management believed that many of the complex technical issues had been resolved; however, the Company had not obtained Food and Drug Administration ("FDA") approval of this technology. Therefore, the risk of not achieving commercialization was not only a developmental risk, but a regulatory risk as well. The work of a full project, which included demonstrating feasibility, defining the project, design, development, verification and clinical testing, and regulatory submission and approval, would need to be completed prior to a launch of a product based on this technology. In the second quarter of 2003, as originally anticipated, the Company obtained FDA clearance to market and sell its pregnancy test that uses the digital-based technology.

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. During 2002, the Company finalized all restructuring activities and recorded an additional $1,819 in exit costs. The additional exit costs were recorded as adjustments to the Unipath business purchase price. As of December 31, 2003, $1,347 (adjusted for foreign exchange effect) in exit costs remained unpaid.

*(g) Pro Forma Financial Information*

The following table presents selected unaudited financial information of the Company, including the Abbott business, ABI, Ostex, Wampole, and IMN as if the acquisitions of these entities had occurred on January 1, 2002. Pro forma results exclude adjustment for SMB as the acquisition did not materially affect the Company's results of operations. The unaudited pro forma results are not necessarily indicative of the results that would have occurred had the above acquisitions been consummated on January 1, 2002 or future results.



| | 2003 | 2002 |
|---|---|---|
| | (unaudited and restated) | |
| Pro forma net revenue | $ 350,123 | $ 343,500 |

| | 2003 | 2002 |
|---|---|---|
| Pro forma income (loss) before accounting change | $ 15,056 | $ (15,801) |
| Cumulative effect of a change in accounting principle | | (12,148) |
| Pro forma net income (loss) | $ 15,056 | $ (27,949) |
| **Pro forma income (loss) available to common stockholders basic:(1)** | | |
| Pro forma income (loss) before accounting change | $ 14,099 | $ (27,749) |
| Pro forma net income (loss) | $ 14,099 | $ (39,897) |
| **Pro forma income (loss) available to common stockholders diluted:(1)** | | |
| Pro forma income (loss) before accounting change | $ 14,279 | $ (27,749) |
| Pro forma net income (loss) | $ 14,279 | $ (39,897) |
| **Pro forma income (loss) per common share basic:** | | |
| Pro forma income (loss) before accounting change | $ 0.78 | $ (2.01) |
| Pro forma net income (loss) | $ 0.78 | $ (2.90) |
| **Pro forma income (loss) per common share diluted:** | | |
| Pro forma income (loss) before accounting change | $ 0.70 | $ (2.01) |
| Pro forma net income (loss) | $ 0.70 | $ (2.90) |

(1) Earnings per share are computed as described in Note 11.



**(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 2001, the Company recorded amortization expense of $398 related to goodwill. This amortization expense was allocated to general and administrative expenses in the accompanying consolidated statement of operations in 2001. The following table presents the loss from continuing operations and net loss of the Company, as if no amortization of goodwill was recorded under SFAS No. 142 in this period:

| | 2001 |
|---|---|
| Loss from continuing operations | $ (24,789) |
| Add back: Goodwill amortization, net of tax | 398 |
| Adjusted loss from continuing operations | $ (24,391) |
| Net loss | $ (24,731) |
| Add back: Goodwill amortization, net of tax | 398 |

| | 2001 |
|---|---|
| Adjusted net loss | $ (24,333) |
| **Adjusted loss per common share basic and diluted:** | |
| Adjusted loss from continuing operations | $ (3.83) |
| Adjusted net loss | $ (3.82) |

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, representing the remaining goodwill related to its reporting unit that comprises the nutritional supplement lines the Company acquired in 1997. This amount represented the excess of the carrying value over the fair value of such asset. The fair value was determined using a combination of the income approach and the market approach of valuing a business. The income approach valued the business by discounting projected future cash flows and the market approach valued the security underlying the business by comparing it to those of similar businesses. The most significant facts and circumstances that led to the conclusion of this impairment were (a) future cash flows from these nutritional supplement lines are expected to be reduced, (b) selling, general and administrative expenses relating to these nutritional supplement lines are forecasted to increase as a percentage of sales, and (c) 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 statement of operations in 2002.

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 $12,682 during the first quarter of 2002, which was included in operating expenses in the accompanying statement of operations in 2002. The remaining carrying value of these intangible assets was $3,858 at December 31, 2003, which is being amortized over the remaining useful life of the intangible asset of 18 years.

**(6) Long-term Debt**

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

| | December 31, | |
|---|---|---|
| | 2003 | 2002 |
| Senior credit facilities | $ 124,834 | $ 52,960 |
| 10% Subordinated notes | 20,000 | 20,000 |
| 9% Subordinated notes | 9,000 | 9,000 |
| 3% Convertible notes | 6,000 | 6,000 |
| IMN credit facilities | 13,075 | 11,741 |
| IMN bonds payable | 1,450 | 2,655 |
| Other | 478 | 521 |
| | 174,837 | 102,877 |

| | December 31, | |
|---|---|---|
| Less: Unamortized original issue discount | 944 | 1,144 |
| Less: Current portion | 14,055 | 17,200 |
| | $ 159,838 | $ 84,533 |

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, of which $44,111 was used to prepay the outstanding principal balances and any accrued and unpaid interest on the term loans and line of credit under a series of former credit agreements (Note 6(f)). On August 27, 2003, to finance the cash portion of its acquisition of ABI (Note 4(b)), the Company amended the senior credit agreement, whereby the borrowing capacity under the credit facilities was increased to $70,000. On September 30, 2003, to finance the cash portion of its acquisition of the Abbott business (Note 4(a)), the Company further amended its senior credit agreement, whereby the borrowing capacity under the credit facilities was further increased to $135,000. The amended senior



credit agreement of September 30, 2003 consisted of two U.S. term loans, Term Loan A for $35,075 and Term Loan B for $40,000, a European term loan for $9,900, a U.S. revolving line of credit of up to $25,000, and a European revolving line of credit of up to $25,000. Aggregate borrowings as of December 31, 2003 amounted to $84,975 under the term loans and $39,859 under the revolving lines of credit. The aggregate unused portion of the revolving lines of credit totaled $10,141 as of December 31, 2003.

On February 10, 2004, all outstanding borrowings and accrued and unpaid interest under the senior credit agreement, aggregating $125,046, were prepaid with the proceeds from the Company's sale of $150,000 of 8.75% senior subordinated notes (the "Bonds"or "Bond issuance") (Note 6(h)). The Company retained the $50,000 availability under the revolving lines of credit, subject to continued covenant compliance, and may repay any future borrowings under the revolving lines of credit at any time but in no event later than March 31, 2008. The Company is required to make mandatory prepayments under the senior credit facilities if it meets certain cash flow thresholds, issues equity securities or subordinated debt, or sells assets not in the ordinary course of business.

The Company treated the prepayment of the outstanding borrowings under the senior credit facilities, using the proceeds form the Bond offering, as a refinancing in accordance with SFAS No. 6, *Classification of Short-Term Obligations Expected to Be Refinanced*. Therefore, the outstanding principal balances under the senior credit facilities, that were originally due to be repaid within one year, were reclassified from current to long-term liabilities in the accompanying consolidated balance sheet at December 31, 2003.

Borrowings under the credit facilities bear interest at either (i) the London Interbank Offered Rate ("LIBOR"), as defined in the agreement, plus applicable margins or, at the Company's option, (ii) a floating Index Rate, as defined in the agreement, plus applicable margins. Applicable margins if the Company chooses to use the LIBOR or the Index Rate can range from 3.25% to 4.50% or 2.00% to 2.75%, respectively, depending on the quarterly adjustments that are based on the Company's consolidated financial performance, commencing with the quarter ending March 31, 2004. As of December 31, 2003, the interest rate under the revolving lines of credit, including the applicable margin, was 5.14%. Interest rates ranging from 5.14% to 5.64% were applicable to borrowings under the term loans at December 31, 2003. The Company recorded interest expense, including amortization of deferred financing costs, under these senior credit facilities in the aggregate amount of $4,602 and $521 in 2003 and 2002, respectively. On February 10, 2004, in connection with the prepayment of the outstanding balances under the senior term loans, the Company also recorded interest expense of $3,297 to write-off the remaining related unamortized deferred financing costs of $2,847 and to expense a financing fee of $450 paid to the banks.

Borrowings under the senior credit facilities are secured by the stock of certain of the Company's U.S. and European subsidiaries, substantially all 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 IMN, 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 agreement

currently prohibits the payment of dividends. As of December 31, 2003, the Company was in compliance with the covenants.

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

On September 20, 2002, the Company sold units ("Units") having an aggregate purchase price of $20,000 to private investors to help finance the Wampole acquisition (Note 4(d)). Each Unit consisted of (i) a 10% subordinated promissory note (a "10% Subordinated Note") in the principal amount of $50 and (ii) a warrant to acquire 0.4 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 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, which started on 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 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 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 and a warrant to purchase 38 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 of $302, 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 $2,465 and $693 in 2003 and 2002, respectively.

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 Units that aggregated $1,850 in principal amount and warrants to purchase an aggregate of 15 shares of the Company's common stock.

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

On September 20, 2002, also in connection with the financing of the Wampole acquisition (Note 4(d)), the Company sold subordinated promissory notes in an aggregate principal amount of $9,000 (the "9% Subordinated Notes") and subordinated convertible promissory notes in an aggregate principal amount of $6,000 (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, which started on October 1, 2002. The Company recorded interest expense, including amortization of deferred financing costs, on these notes of $1,003 and $282 in 2003 and 2002, respectively. The 3% Convertible Notes mature on September 20, 2008, subject to acceleration in certain circumstances. On February 10, 2004, the Company prepaid the 9% Subordinated Notes with the proceeds from the Bond issuance (Note 6(h)). The total payment made on the prepayment date aggregated $9,271, which represented the principal balance outstanding plus accrued and unpaid interest as well as a prepayment penalty of $180, which equated to 2% of the principal balance repaid. The prepayment penalty along with the remaining unamortized deferred financing cost write-off, aggregating $216, was charged to interest expense in February 2004.

Upon maturity of the 3% Convertible Notes, the Company has the option to repay the notes 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 3% Convertible Notes are expressly subordinated to up to $150,000 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 3% Convertible Notes rank equally 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.

*(d) IMN Credit Facilities*

In connection with the acquisition of IMN, the Company assumed IMN's borrowings under a senior credit agreement ("IMN Credit Agreement"). Pursuant to the IMN Credit Agreement, as amended, IMN can borrow up to $15,000 under a revolving credit commitment and $4,200 under a term loan commitment, subject to specified borrowing base limitations. As of December 31, 2003, IMN had $10,783 in outstanding borrowings under the revolving credit commitment and $2,292 in outstanding principal amount under the term loan. Borrowings under the IMN Credit Agreement will mature on October 15, 2004 and are automatically extended for one year at each maturity date unless a ninety day termination notice is given in writing by either party to the agreement. 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, 2003, the interest rates on the loan facilities ranged from 4.92% to 5.50%. Interest expense, including amortization of deferred financing costs, on IMN's credit facilities was $835 and



$661 in 2003 and 2002, respectively. At December 31, 2003, availability under the revolving credit commitment amounted to $426, which had been reduced by borrowing base limitations.

The notes are collateralized by substantially all of IMN's assets. The IMN Credit Agreement requires IMN to maintain minimum tangible net worth and contains various restrictions customary in such financial arrangements, including limitations on the payment of cash dividends. As of December 31, 2003, IMN was in compliance with such requirements and restrictions.

*(e) IMN Bonds Payable*

Also in connection with the acquisition of IMN, the Company assumed IMN's bonds payable ("IMN Bonds"), which had an aggregate outstanding balance of $1,450 as of December 31, 2003. The bonds are payable in various installments through June 30, 2007 and the bonds payable balance bear interest at 6.90%. Interest on the bonds payable balance is payable semi-annually and IMN recorded interest expense, including amortization of deferred financing costs, on such bonds of $121 and $214 during 2003 and 2002, respectively. The bonds are collateralized by certain property and equipment of IMN. Additionally, the bonds require IMN to maintain letters of credit from a bank equal to the outstanding principal balances of the bonds and the fees on such letters was .85% per annum until November 30, 2003 and 1% per annum thereafter.

*(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 "Former Credit Agreements") with a bank and entities related to such bank for various credit facilities in the aggregate amount of $65,000, as amended. The proceeds of the Former Credit Agreements were used to finance a portion of the cash used to acquire the Unipath business (Note 4(f)). The per annum interest rate on the loans was 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, under the Former Credit Agreement, interest at 4.00% per annum was expensed and deferred on the junior loan. As part of the Former Credit Agreements, the Company issued the bank a warrant to acquire 65 shares of the Company's common stock at nominal cost. The Company had allocated $1,105 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 and $134, respectively.

On November 14, 2002, the Company prepaid the outstanding principal balances and any unpaid interest under the Former Credit Agreements, aggregating $44,111, with proceeds from the senior credit facilities obtained on that date (Note 6(a)). The Company accounted for the prepayment as an early extinguishment of debt. Accordingly, on November 14, 2002, the Company accelerated the amortization of the remaining unamortized original issue discount and deferred financing costs of $972 and $2,237, respectively, which were recorded as a component of interest expense 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 for the purpose of funding its acquisition of the Unipath business (Note 4(f)). The original maturity date of the Subordinated Notes was April 1, 2002, with an extension option, and interest accrued at 12% per annum, or 18% if and when 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 $3,243 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 shares of the Company's common stock at an exercise price of $18.12 per share. The Company allocated $672 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 the original issue discount, beneficial conversion feature and deferred financing costs was $2,974 and $564, respectively.

On March 6, 2002, the Company prepaid the Subordinated Bridge Notes, which had an aggregate outstanding balance of $20,000, and related accrued interest of $568. 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 $9,600 related to the gain on early extinguishment of debt as other income (expense), net, and $1,260 related to the unamortized original issue discount, initial beneficial conversion feature and deferred financing costs as additional interest expense. In accordance with EITF Issue Nos. 98-5 and 00-27, the gain of $9,600 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 Subordinated Bridge Note and holds a warrant, issued in connection with such note, to purchase 28 shares of the Company's common stock.

*(h) $150,000 Senior Subordinated Notes*

On February 10, 2004, the Company completed the sale of $150,000 of 8.75% Bonds, due 2012 in a private placement to qualified institutional buyers. Net proceeds from this offering amounted to $145,950 which was net of underwriters' commissions of $4,050. Of the net proceeds, $125,259 was used to repay all of the outstanding indebtedness and related financing fees under the senior credit facilities (Note 6(a)) and $9,180 was used to prepay the outstanding 9% Subordinated Notes and related



prepayment penalties (Note 6 (c)). The Company retained the remaining unused proceeds for Bond offering expenses and general corporate purposes.

The Bonds accrue interest from the date of their issuance, or February 10, 2004, at the rate of 8.75% per year. Interest on the Bonds will be payable semi-annually in arrears on each February 15 and August 15, commencing on August 15, 2004. The Company may redeem the Bonds, in whole or in part, at any time on or after February 15, 2008, at a redemption price equal to 100% of the principal amount plus a premium declining ratably to par, plus accrued and unpaid interest. In addition, prior to February 15, 2007, the Company may redeem up to 35% of the aggregate principal amount of the Bonds issued with the proceeds of qualified equity offerings at a redemption price equal to 108.75% of the principal amount, plus accrued and unpaid interest. If the Company experiences a change of control, it may be required to offer to purchase the Bonds at a purchase price equal to 101% of the principal amount, plus accrued and unpaid interest.

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

The Bonds are guaranteed by all of the Company's domestic subsidiaries that are guarantors or borrowers under the senior credit facilities which excludes its subsidiary IMN in New Jersey. The guarantees are general unsecured obligations of the guarantors and are subordinated in right of payment to all existing and future senior debt of the applicable guarantors, which includes their guarantees of, and borrowings under the Company's senior credit facilities. See Note 18 for guarantor financial information.

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

*(i) Maturities of Long-Term Debt*

The following is a summary of the maturities of long-term debt outstanding on December 31, 2003:

| | |
|---|---|
| 2004 | $ 14,055 |
| 2005 | 548 |
| 2006 | 300 |
| 2007 | 100 |
| 2008 | 26,000 |
| Thereafter | 133,834 |
| | 174,837 |
| Less: Unamortized original issue discount | (944) |
| | $ 173,893 |



**(7) Capital Leases**

The Company's subsidiary IMN 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 IMN entered into prior to it being acquired by the Company. The aggregate monthly minimum payments remaining under this capital lease are $2,643 as of December 31, 2003. In addition, the Company has various other capital leases for certain machinery and equipment and computer equipment that expire at various dates through 2006, with remaining aggregate monthly minimum payments of $121. 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, 2003:

| | |
|---|---|
| 2004 | $ 636 |
| 2005 | 609 |
| 2006 | 593 |
| 2007 | 585 |
| 2008 | 341 |
| Total future minimum lease payments | 2,764 |
| Less: Imputed interest | (476) |
| Present value of future minimum lease payments | 2,288 |
| Less: Current portion | (457) |
| | $ 1,831 |

At December 31, 2003, the capitalized amounts of the building, machinery and equipment and computer equipment under the capital leases were as follows:

| | |
|---|---|
| Machinery, laboratory equipment and tooling | $ 152 |

| | |
|---|---|
| Buildings | 2,186 |
| Computer equipment | 22 |
| | 2,360 |
| Less: Accumulated amortization | (673) |
| | $ 1,687 |

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 terms to the Company's current plans. The Company's results for 2001 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 $308, $125 and $15 in 2003, 2002 and 2001, respectively.

*(b) UK Pension Plans*

The Company's subsidiary in England, Unipath Ltd., adopted a pension plan (the "Unipath Pension Scheme") in December 2002. The Unipath Pension Scheme consists of two parts: (i) the defined benefit section (the "Defined Benefit Plan"), and (ii) the defined contribution section (the "Defined Contribution Plan"). Employees of Unipath Ltd. were allowed to join the Unipath Pension Scheme starting on December 1, 2002.

As part of the purchase agreement of the Unipath business, the Company agreed to establish a new defined benefit pension plan for the acquired employees based in England, who are former participants of the Unilever pension plan (the "Acquired UK Employees"), and to continue to accumulate benefits under such plan for a period of at least three years after the acquisition date of the Unipath business. Consequently, the Defined Benefit Plan was established as part of the Unipath Pension Scheme, which covers the Acquired UK Employees during the last two years of the three year post-acquisition period starting on December 1, 2002. During the first year of the three year post-acquisition period through November 2002, the Acquired UK Employees continued to accumulate benefits under the Unilever pension plan, to which Unipath Ltd. contributed $1,919 in that period.

At the time of the acquisition, 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 as part of the purchase price of the Unipath business (withdrawal obligation). Such unfunded pension liability represented the excess of the benefit obligation, or $20,485, over the fair value of the plan assets, or $16,800, initially allocated by Unilever to the plan assets for the benefit of the Acquired UK Employees. As some of the Acquired UK Employees were terminated under the Company's restructuring plan upon acquisition, the unfunded pension liability initially recorded by the Company, or $3,685, was reduced by the portion of these employees' severance pay-out that represented pension benefits, or $1,051, which was reclassified to severance costs for purposes of aggregating the purchase price of the Unipath business (Note 4(f)).

The Acquired UK Employees may also elect, at their option, to transfer contributions and benefits from the Unilever pension plan to the Defined Benefit Plan. The Company believes that the UK Defined Benefit Plan is no less favorable to the Acquired UK Employees than Unilever's plan and the Company intends to maintain this benefit for a period of three years from the acquisition date.

Nevertheless, the Company and Unilever are currently engaged in litigation over this issue and the outcome of such litigation cannot be estimated at this time.

As of December 31, 2003, the number and identities of Acquired UK Employees who may elect to transfer their contributions and benefits to the Defined Benefit Plan are unknown. In addition, the current dispute between Unilever and the Company over certain terms of the Defined Benefit Plan could affect the amount of withdrawal obligation, if any, required by the Company, if and when the Acquired UK Employees elect to transfer their contributions and benefits from Unilever's pension plan. Therefore, the withdrawal obligation of the Company for such Acquired UK Employees, if any, who will elect to participate in and transfer their pension assets from Unilever's pension plan to the Defined Benefit Plan was not estimable at December 31, 2003. As a result, the remaining pension liability balance of $2,634, that was initially recorded as part of the purchase price of the Unipath business and included in other liabilities in the accompanying consolidated balance sheet, may need to be adjusted upon settlement of the disputed terms of the plan and the election by the Acquired UK Employees to transfer their contributions and benefits from Unilever's pension plan to the Defined Benefit Plan, if any.

The Defined Benefit Plan is contributory and is established solely for the purpose of substituting Unilever's pension plan for the Acquired UK Employees. Therefore, only Acquired UK Employees are eligible to join the Defined Benefit Plan. At the end of 2004, the end of the three year post-acquisition period, the Defined Benefit Plan will be frozen and all participants will be transferred into the Defined Contribution Plan while their accumulated benefits and plan assets remain in the Defined Benefit Plan. Until then, only new employees are eligible to participate in the Defined Contribution Plan. In 2003, Unipath Ltd. contributed $172 to the Defined Contribution Plan, which was recognized as an expense in the accompanying consolidated statement of operations. In 2002, contributions into the Defined Contribution Plan were nominal.

Because the Defined Benefit Plan had only been operating for one month during 2002, changes in benefit obligations and plan assets and net amount recognized in the accompanying consolidated financial statements during 2002 and at December 31, 2002 were nominal. The following table sets forth an analysis of the changes in the benefit obligation, the plan assets and the funded status of the Defined Benefit Plan during 2003:



| | | |
|---|---|---|
| **Change in benefit obligation** | | |
| Benefit obligation at beginning of year | $ | 171 |
| Service cost | | 1,481 |
| Interest cost | | 62 |
| Plan participants' contributions | | 559 |
| Actuarial loss | | 445 |
| Benefits paid | | (151) |
| Benefit obligation at end of year | $ | 2,567 |
| **Change in plan assets** | | |
| Fair value of plan assets at beginning of year | $ | 155 |
| Actual return on plan assets | | 37 |
| Employer contribution | | 1,364 |
| Plan participants' contributions | | 559 |
| Benefits paid | | (151) |
| Fair value of plan assets at end of year | $ | 1,964 |
| Funded status | $ | (603) |
| Unrecognized net actuarial loss | | 472 |
| Net amount recognized | $ | (131) |

The net amount recognized in the accompanying consolidated balance sheet that relates to the Defined Benefit Plan during 2003 consists of:

| | | |
|---|---|---|
| Accrued benefit liability | $ | (565) |

| | |
|---|---|
| Accumulated other comprehensive income | 434 |
| Net amount recognized | $ (131) |

The measurement date used to determine plan assets and benefit obligations for the Defined Benefit Plan was December 31, 2003. Accumulated benefit obligation for the Defined Benefit Plan amounted to $2,530 at December 31, 2003.

The following table provides the weighted-average actuarial assumptions:

| | |
|---|---|
| **Assumptions used to determine benefit obligations at December 31, 2003** | |
| Discount rate | 5.50% |
| Rate of compensation increase | 4.25% |
| **Assumptions used to determine net periodic benefit cost in 2003** | |
| Discount rate | 5.70% |
| Expected return on plan assets | 6.20% |
| Rate of compensation increase | 3.80% |



The actuarial assumptions are reviewed on an annual basis. The overall expected long-term rate of return on plan assets assumption was determined based on historical investment return rates on portfolios with a high proportion of equity securities.

The annual cost of the Defined Benefit Plan is as follows:

| | |
|---|---|
| Service cost | $ 1,481 |
| Interest cost | 62 |
| Expected return on plan assets | (64) |
| Net periodic benefit cost | $ 1,479 |

The plan assets of the Defined Benefit Plan comprise of a mix of stocks and fixed income securities and other investments. At December 31, 2003, these stocks and fixed income securities represented 55% and 23%, respectively, of the market value of the pension assets. The trustee of the Defined Benefit Plan has adopted a long-term investment strategy of investing 37.5% in UK equities, 37.5% in equities outside of the UK and 25% in corporate bonds. The plan assets are being switched to these allocations as market opportunities arise. In addition, the funding objective is to maintain a funding level of at least 100% on an ongoing basis.

Unipath Ltd. expects to contribute approximately 800 British Pounds Sterling (or $1,424 at December 31, 2003) to the Defined Benefit Plan in 2004, subject to the withdrawal obligation if and when the Acquired UK Employees elect to transfer from Unilever's pension plan and the Company's settlement on the terms of the Defined Benefit Plan with Unilever.

*(c) 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 $127, $96 and $12 during 2003, 2002 and 2001, respectively. As of December 31, 2003, Orgenics had made fund payments in excess of the liability by $7, which was included in prepaid expenses and other current assets in the accompanying balance sheet. The balance of unfunded severance liability was $10 at December 31, 2002, which the Company had accrued for on that date.

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, 2003 and 2002.

**(9) Derivative Instrument**

The Company entered into an interest rate swap agreement with one of its lenders, effective February 25, 2002, which was intended to protect 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%. Because the interest rate swap agreement did not qualify as a hedge for accounting purposes under SFAS No. 133 and related amendments, the Company recorded income of $528 and expense of $1,223 during 2003 and 2002, respectively, to mark to market this interest rate swap agreement. The adjustment to fair value of the interest rate swap agreement was recorded as a component of interest expense in the accompanying consolidated statements of operations and the fair value was included as a component of accrued expenses and other current liabilities in the accompanying consolidated balance sheets.

**(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 2027. The following schedule outlines future minimum annual rental payments under these leases at December 31, 2003:

| | |
|---|---|
| 2004 | $ 6,422 |
| 2005 | 5,557 |
| 2006 | 4,963 |
| 2007 | 4,713 |
| 2008 | 4,231 |
| Thereafter | 40,361 |
| | $ 66,247 |

Rent expense relating to operating leases was approximately $5,755, $4,311 and $1,029 during 2003, 2002 and 2001, respectively.

The operations of the Unipath business in England are currently housed in a 150 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 British Pounds Sterling to 1,560 British Pounds Sterling (approximately $2,599 to $2,777) 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. If Unilever is unable to successfully assign the lease to the Company or otherwise enable the Company to realize the benefit of its lease of the Bedford facility, the Company may be forced to renegotiate a lease of this facility on substantially less favorable terms, seek alternative, more costly means of producing its products or suffer other adverse effects to its business.



*(b) Capital Expenditure Commitments*

At December 31, 2003, the Company had total outstanding non-cancelable equipment purchase commitments of $2,084.

*(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. Potential product liability claims may exceed the amount of the Company's 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 the Company is held liable for a claim, against which it is not indemnified or for damages exceeding the limits of its insurance coverage, such liability could have a material adverse effect on its business, financial condition and results of operations.

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. In addition, a final ruling on such counterclaims against the Company could have a material adverse impact on its sales, operations or financial performance.

The Company previously had several lawsuits pending against Pfizer Inc. and certain other parties including Princeton BioMeditech ("PBM") alleging, among other things, that pregnancy tests manufactured or sold by the defendants infringe patents owned by the Company. In early June 2003, the Company settled the litigation against Pfizer. However, its claims against PBM, a co-defendant in one of the infringement suits against Pfizer and the subject of two other related infringement suits initiated by the Company, remain active. PBM has brought several counterclaims against the Company. The counterclaims allege, among other things, that the Company has breached various obligations to PBM arising out of a joint venture with the Company. The Company believes that it has strong defenses to all of the counterclaims and is defending them vigorously.

In February 2004, Quidel Corporation was served in Germany with a suit that the Company's subsidiary, Inverness Medical Switzerland, GmbH ("IMS"), had filed in January 2004 seeking damages and injunction for infringement of certain of the Company's patents. In response, on February 20, 2004, Quidel named the Company and its subsidiaries IMS and ABI as defendants in a suit filed by Quidel. Quidel alleges that the Company is infringing its patent that was issued in 1990 titled "Lateral Flow, Non-Bibulous Membrane Assay Protocols." Quidel also asked the Court for a declaratory finding that Quidel does not infringe certain patents owned by IMS and certain other patents owned by co-defendant Armkel LLC and that these patents are invalid and/or unenforceable. Quidel seeks injunctive relief and damages, and has indicated its intent to file a motion for preliminary injunction, the scope of which has not been disclosed. In early March, 2004, the Company filed an answer claiming that Quidel's claims are without merit and a counterclaim seeking damages and injunctive relief for Quidel's infringement of these patents. The Company also filed a separate action against Quidel in the



same court alleging infringement of certain other patents and seeking injunctive relief and damages. The Company intends to vigorously defend the Quidel claims and vigorously prosecute the infringement counterclaims and separate claims to enforce its intellectual property rights.

*(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, 2003 and 2002 was $200. Orgenics does not have any liability to the State of Israel for amounts received in support of unsuccessful programs or unsaleable products. During 2001, Orgenics paid $169 in royalties to the Chief Scientist. There were no royalties paid during 2003 and 2002.



**(11) Earnings Per Share**

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

| | 2003 | 2002 | 2001 |
|---|---|---|---|
| | (restated) | (restated) | |
| ***Numerator:*** | | | |

| | 2003 | 2002 | 2001 |
|---|---|---|---|
| Income (loss) from continuing operations | $ 12,269 | $ (21,875) | $ (24,789) |
| Dividends, redemption interest and amortization of beneficial conversion feature related to Series A Preferred Stock (Note 12(b)) | (958) | (11,948) | |
| Income (loss) from continuing operations available to common stockholders | 11,311 | (33,823) | (24,789) |
| Income from discontinued operations | | | 58 |
| Income (loss) before accounting change available to common stockholders | 11,311 | (33,823) | (24,731) |
| Cumulative effect of a change in accounting principle | | (12,148) | |
| Net income (loss) available to common stockholders basic | 11,311 | (45,971) | (24,731) |
| Interest related to convertible debt | 180 | | |
| Net income (loss) available to common stockholders diluted | $ 11,491 | $ (45,971) | $ (24,731) |
| ***Denominator:*** | | | |
| Denominator for basic income (loss) per share weighted average shares (Note 2(k)) | 15,711 | 9,940 | 6,368 |
| Effect of dilutive securities: | | | |
| Employee stock options | 635 | | |
| Warrants | 213 | | |
| Restricted stock and escrow shares | 931 | | |
| Convertible promissory notes | 344 | | |
| Potential dilutive common shares | 2,123 | | |
| Denominator for dilutive income (loss) per share adjusted weighted average shares and assumed conversions | 17,834 | 9,940 | 6,368 |
| ***Income (loss) per share basic:*** | | | |
| Income (loss) from continuing operations | $ 0.72 | $ (3.40) | $ (3.89) |
| Income from discontinued operations | | | 0.01 |
| Income (loss) before accounting change | 0.72 | (3.40) | (3.88) |
| Cumulative effect of a change in accounting principle | | (1.22) | |
| Net income (loss) | $ 0.72 | $ (4.62) | $ (3.88) |
| ***Income (loss) per share diluted:*** | | | |
| Income (loss) from continuing operations | $ 0.64 | $ (3.40) | $ (3.89) |
| Income from discontinued operations | | | 0.01 |
| Income (loss) before accounting change | 0.64 | (3.40) | (3.88) |
| Cumulative effect of a change in accounting principle | | (1.22) | |
| Net income (loss) | $ 0.64 | $ (4.62) | $ (3.88) |

| 2003 | 2002 | 2001 |
|---|---|---|



The Company had the following potential dilutive securities outstanding on December 31, 2003: (a) options and warrants to purchase an aggregate of 800 shares of the Company's common stock at a weighted average exercise price of $22.87 per share, and (b) Series A Preferred Stock convertible into an aggregate of 416 shares of the Company's common stock. Such potential dilutive securities were not included in the calculation of diluted income per share in 2003 because the inclusion thereof, together with the add back of the Series A Preferred Stock redemption interest and dividends, would be antidilutive.

The Company had the following potential dilutive securities outstanding on December 31, 2002: (a) options and warrants to purchase an aggregate of 3,553 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 shares of the Company's common stock, (c) 3% Convertible Notes convertible into an aggregate of 344 shares of the Company's common stock, (d) 1,214 shares of unvested restricted common stock issued to certain executive officers, and (e) 16 shares of common stock held in escrow. Potential dilutive securities were not included in the computation of diluted loss per share in 2002 because the inclusion thereof would be antidilutive.

The Company had the following potential dilutive securities outstanding on December 31, 2001: (a) options and warrants to purchase an aggregate of 2,576 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 an aggregate of 3,990 shares of the Company's common stock, (c) 1,818 shares of unvested restricted common stock issued to certain executive officers, and (d) 32 shares of common stock held in escrow. Potential dilutive securities were not included in the computation of diluted loss per share in 2001 because the inclusion thereof would be antidilutive.

**(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, 2003, the Company had 50,000 shares of common stock, $0.001 par value, authorized, of which 19,640 shares were issued and outstanding, 416 shares were reserved for issuance upon conversion of outstanding Series A Preferred Stock, 344 shares were reserved for issuance upon conversion of outstanding 3% Convertible Notes, 3,985 shares were reserved for issuance upon grant and exercise of stock options under current stock option plans and 712 shares were reserved for issuance upon exercise of outstanding warrants.

*(b) Preferred Stock*

As of December 31, 2003, the Company had 5,000 shares of preferred stock, $0.001 par value, authorized, of which 2,667 shares were designated as Series A Preferred Stock, $0.001 par value. On March 6, 2002, the Company sold to private investors 532 shares of Series A Preferred Stock at $39.01



per share for gross proceeds of $20,750. On December 20, 2001, the Company sold to private investors 1,995 shares of Series A Preferred Stock at $30.00 per share for gross proceeds of $59,850 to help finance its acquisition of the Unipath business (Note 4(f)). 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 627 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, 2003, 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, 2003. During 2003 and 2002, 115 and 2,204 shares of Series A Preferred Stock were converted into 230 and 4,408 shares of the Company's common stock and 208 shares of Series A Preferred Stock remained outstanding as of December 31, 2003.

Starting on the second anniversary of the original issue date, the Company had the right to 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. Consequently, as of January 14, 2004, the Company converted all remaining outstanding shares of the Series A Preferred Stock into shares of common stock at a conversion rate of two shares of common stock per share of Series A Preferred Stock.

Each share of Series A Preferred Stock accrued dividends on a quarterly basis at $2.10 per annum, but only on those trading days when the closing price of the Company's common stock is less than $15.00. As a result, the Company accrued dividends of $33 and $326 during 2003 and 2002, respectively, 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 were payable only if declared by the board of directors. No dividends were declared by the board of directors prior to the conversion of all outstanding shares of Series A Preferred Stock on January 14, 2004. In addition, 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 respective issuance dates. 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 two issuances of Series A Preferred Stock of $2,867 and $7,980, respectively, which was 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 2003 and 2002, the Company amortized $509 and $9,575, respectively, of such discount, of which $362 and $8,811, respectively, 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. Upon the conversions of the remaining outstanding Series A Preferred Stock on January 14, 2004, the remaining unamortized discount of $739 was accelerated and charged to accumulated deficit.



Because the Series A Preferred Stock could have been redeemed upon a vote by the holders of at least 66$^{2}/_{3}$% of the outstanding shares on or after June 30, 2011, the Company classified the outstanding Series A Preferred Stock outside of stockholders' equity in the accompanying consolidated balance sheets and statements of stockholders' equity and comprehensive income (loss). The redemption price per share of Series A Preferred Stock would have been equal to $30.00 plus accrued redemption interest calculated at 5% per annum from the date of issuance. The Company recorded accrued redemption interest of $415 and $2,048 in 2003 and 2002, respectively, which reduced earnings available to common stockholders in the computation of earnings per share. The amount of the accrued redemption 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, subject to adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization, plus any undeclared or unpaid dividends.

Each holder of Series A Preferred Stock has two votes for every one share of Series A Preferred Stock, which is currently 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 5,324 shares of common stock and other awards, as amended. The 2001 Plan is 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 non-employee directors and automatic vesting acceleration of all options and stock appreciation rights upon a change in control, as defined by the 2001 Plan. As of December 31, 2003, there are 587 shares available for future grant under the 2001 plan.

On August 15, 2001, the Company sold to its chief executive officer 1,168 shares of restricted common stock at a price of $9.13 per share. Two-thirds of the restricted stock, or 779 shares, vest ratably over 36 months; the remaining one-third, or 389 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 total interest under the promissory note is fully recourse to the Company's chief executive officer. 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 is due and payable on August 16, 2006 and bears interest at an annual rate of 4.99%. Interest income recorded under this note amounted to $532, $532 and $200 in 2003, 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 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 shares of his nonqualified stock options in the Company. Because the repurchase rights on unvested shares are at fair value subsequent to the amendment in February 2002, 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 $10,145 and $451 in 2002 and 2001, respectively, which was recorded as stock-based compensation in the accompanying consolidated statements of operations. Additionally, this amendment resulted in a new measurement date for this security. In the event that the employee ceases employment with the Company prior to the full vesting of this security, additional compensation expense would be recorded.

In August 2001, the Company granted two nonqualified stock options to purchase an aggregate of 779 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 are due and payable on December 4, 2006 and 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 $160, $160 and $12 in 2003, 2002 and 2001, respectively. Shares issued upon exercise vest ratably over 36 months. Under certain circumstances, the Company may repurchase unvested shares at the then fair value. One of these executive officers exercised 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 $9,346 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 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 Former 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 Former Credit Agreements. In consideration of his entry into this lock up agreement, the Company granted the chief executive officer an option to acquire 115 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 shares of the Company's common stock. The Company determined that the entity controlled by the Company's chief executive officer and the chief executive officer

himself should be viewed as one in the same as 1) this entity's participation in the financing was on the same basis and terms as all other investors, 2) only the Company's chief executive officer and this entity were required to enter into lockup agreements with the bank, and 3) only the Company's chief executive officer and his family are owners of this entity. Accordingly, the Company accounted for these warrants issued in accordance with APB Opinion No. 25. As a result, no compensation expense was recorded as these options had no intrinsic value.

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.

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

| | 2003 | | 2002 | | 2001 | |
|---|---|---|---|---|---|---|
| | Options | Weighted Average Exercise Price | Options | Weighted Average Exercise Price | Options | Weighted Average Exercise Price |
| Outstanding at January 1 | 2,754 | $ 14.84 | 1,955 | $ 12.77 | 886 | $ 2.06 |
| Granted | 1,090 | 18.71 | 1,116 | 17.72 | 2,335 | 12.68 |
| Exercised | (271) | 11.49 | (140) | 4.97 | (1,121) | 12.04 |
| Terminated | (175) | 24.62 | (177) | 17.95 | (145) | 6.55 |
| Outstanding at December 31 | 3,398 | $ 15.85 | 2,754 | $ 14.84 | 1,955 | $ 12.77 |
| Exercisable at December 31 | 1,591 | $ 14.10 | 1,134 | $ 12.25 | 775 | $ 7.55 |

The following represents additional information related to stock options outstanding and exercisable at December 31, 2003:

| | 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 | 10 | 1.79 | $ 0.75 | 10 | $ 0.75 |
| 1.24-1.80 | 160 | 3.32 | 1.46 | 160 | 1.46 |
| 1.88-2.68 | 108 | 5.42 | 2.42 | 108 | 2.42 |
| 2.89-4.32 | 14 | 4.23 | 3.96 | 14 | 3.96 |
| 4.38-6.48 | 37 | 3.82 | 4.82 | 37 | 4.82 |
| 6.67-9.60 | 148 | 8.44 | 9.34 | 50 | 8.88 |
| 10.85-16.20 | 1,585 | 8.32 | 15.15 | 671 | 15.03 |
| 16.32-24.20 | 1,254 | 7.78 | 19.93 | 502 | 19.07 |
| 25.40-35.47 | 65 | 7.87 | 27.47 | 22 | 28.72 |
| 39.59-48.94 | 11 | 3.43 | 42.60 | 11 | 42.60 |
| 59.58-70.93 | 3 | 5.02 | 65.47 | 3 | 65.47 |
| 106.39-139.72 | 2 | 3.76 | 117.88 | 2 | 117.88 |
| 165.96 | 1 | 3.91 | 165.96 | 1 | 165.98 |
| | 3,398 | 7.69 | $ 15.85 | 1,591 | $ 14.10 |

*(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 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, 2003:

| | Number of Shares | Exercise Price | Weighted Average Exercise Price |
|---|---|---|---|
| Warrants outstanding and exercisable, December 31, 2000 | 140 | $ 0.75-7.55 | $ 3.18 |
| Granted | 525 | 0.001-21.28 | 15.06 |
| Exercised | (44) | 3.02-7.55 | 5.06 |
| Warrants outstanding and exercisable, December 31, 2001 | 621 | 0.75-21.28 | 13.09 |
| Granted | 238 | 10.90-13.54 | 13.10 |
| Exercised | (58) | 0.75-7.50 | 0.94 |
| Cancelled | (1) | 6.23 | 6.23 |
| Warrants outstanding and exercisable, December 31, 2002 | 800 | 0.001-21.28 | 13.98 |
| Granted | 10 | 9.89-23.76 | 19.01 |
| Exercised | (97) | 0.001-22.57 | 2.46 |
| Cancelled | (1) | 15.84 | 15.84 |
| Warrants outstanding and exercisable, December 31, 2003 | 712 | $ 3.81-23.76 | $ 15.62 |

The following represents additional information related to warrants outstanding and exercisable at December 31, 2003:

| | Outstanding and Exercisable | | |
|---|---|---|---|
| Exercise Price | Number of Shares | Weighted Average Remaining Contract Life | Weighted Average Exercise Price |
| $3.81-5.57 | 10 | 6.54 | $ 4.77 |
| 7.37-10.90 | 44 | 8.43 | 10.70 |
| 11.55-17.15 | 597 | 4.83 | 15.87 |
| 17.98-23.76 | 61 | 7.31 | 18.51 |
| | 712 | 5.29 | $ 15.62 |

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 shares of the Company's common stock were issued to officers and directors of the Company or entities controlled by these officers and directors and were outstanding at December 31, 2003. The value of warrants issued in connection with debt financings have yielded original issue discounts and additional interest expense of $206 in 2003, $492 in 2002 and $103 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 are 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 shares of common stock under this plan. At December 31, 2003, 92 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 713. No performance targets have been achieved as of December 31, 2003.

**(13) Other Comprehensive Income**

SFAS No. 130, *Reporting Comprehensive Income*, establishes standards for the reporting and display of comprehensive income. In general, comprehensive income combines net income and other changes in equity during the year from non-owner sources. Accumulated other comprehensive income is recorded as a component of stockholders' equity. The following is a summary of the components of and

changes in accumulated other comprehensive income as of December 31, 2003 and in each of the three years then ended:

| | Cumulative Translation Adjustment (Note 2(b)) | Pension Liability Adjustment (Note 8(b)) | Other(i) | Accumulated Other Comprehensive Income(ii) |
|---|---|---|---|---|
| | (restated) | | | (restated) |
| Balance at December 31, 2000 | $ 766 | $ | $ | $ 766 |
| Period change | 901 | | | 901 |
| Balance at December 31, 2001 | 1,667 | | | 1,667 |
| Period change | 4,817 | | | 4,817 |
| Balance at December 31, 2002 | 6,484 | | | 6,484 |
| Period change | 5,627 | (434) | 136 | 5,329 |
| Balance at December 31, 2003 | $ 12,111 | $ (434) | $ 136 | $ 11,813 |

(i) The balance of $136, included in other comprehensive income, represents unrealized gains on available-for-sales securities. The aggregate fair value of such securities was insignificant and was included in prepaid expenses and other current assets in the accompanying consolidated balance sheet at December 31, 2003.

(ii) All of the components of accumulated other comprehensive income relate to the Company's foreign subsidiaries. No adjustments for income taxes were recorded against other comprehensive income as the Company intends to permanently invest in its foreign subsidiaries in the foreseeable future.

**(14) Income Taxes**

The Company's income tax provision in 2003 and 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, the income tax provision represented mainly those recorded by Inverness Medical, Inc. ("IMI"). Income or (loss) from continuing operations before income taxes consists of the following:

| | 2003 | 2002 | 2001 |
|---|---|---|---|
| | (restated) | (restated) | |
| United States | $ 279 | $ (24,672) | $ (13,686) |
| Foreign | 13,159 | 5,480 | (8,969) |
| | $ 13,438 | $ (19,192) | $ (22,655) |

For federal and some state income tax filing purposes, the results of IMI's operations were 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 maintained by IMI and the Company's other subsidiaries were 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.

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 exceeded the threshold. 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, | |
|---|---|---|
| | 2003 | 2002 |
| Deferred tax assets: | | |
| Net operating loss (NOL) and capital loss carryforwards | $ 34,107 | $ 13,791 |
| Tax credit carryforwards | 833 | |
| Nondeductible reserves | 7,020 | 4,419 |
| Nondeductible accruals | 9,132 | 6,106 |
| Nondeductible stock-based compensation | | 192 |
| Difference between book and tax bases of tangible assets | 595 | 1,160 |
| Difference between book and tax bases of intangible assets | 20,313 | 29,171 |
| Gross deferred tax asset | 72,000 | 54,839 |
| Valuation allowance | (66,747) | (48,405) |
| Deferred tax asset | $ 5,253 | $ 6,434 |
| Deferred tax liabilities: | | |
| Difference between book and tax bases of tangible assets | $ 6,116 | $ 4,110 |
| Difference between book and tax bases of intangible assets | 3,002 | 5,255 |
| Deferred tax liability | $ 9,118 | $ 9,365 |
| Net deferred tax liability | $ 3,865 | $ 2,931 |

As of December 31, 2003, the Company had approximately $73,762 of domestic operating loss carryforwards and $20,556 of foreign net operating loss and foreign capital loss carryforwards, which either expire on various dates through 2023 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.

In accordance with SFAS No. 109, the accounting for the tax benefits of acquired deductible temporary differences, which are not recognized at the acquisition date because a valuation allowance is established and which are recognized subsequent to the acquisitions, will be applied first to reduce to zero any goodwill and other noncurrent intangible assets related to the acquisitions. Any remaining benefits would be recognized as a reduction of income tax expense. As of December 31, 2003, $22,525 of the Company's deferred tax asset pertains to acquired companies, the future benefits of which will be applied first to reduce to zero any goodwill and other noncurrent intangible assets related to the

acquisitions, prior to reducing the Company's income tax expense. Included in the valuation allowance, is approximately $1,612 related to certain operating loss carryforwards resulting from the exercise of employee stock options, the tax benefit of which, when recognized, will be accounted for as a credit to additional paid-in capital rather than a reduction of income tax.

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 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, if any, 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 this hypothetical calculation; however, unrecognized foreign tax credit carryforwards may be available to reduce some portion of the U.S. tax liability, if any.

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

| | 2003 | 2002 | 2001 |
|---|---|---|---|
| Current | | | |
| Federal | $ | $ | $ 1,062 |
| State | 419 | 322 | 620 |
| Foreign | 1,465 | 2,357 | 33 |
| | 1,884 | 2,679 | 1,715 |
| Deferred | | | |
| Federal | | | 320 |
| State | | | 99 |
| Foreign | (715) | 4 | |
| | (715) | 4 | 419 |
| Total tax provision | $ 1,169 | $ 2,683 | $ 2,134 |

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

| | 2003 | 2002 (restated) | 2001 |
|---|---|---|---|
| Statutory rate | 35% | (34)% | (34)% |
| Effect of losses and expenses not benefited | 1 | 17 | 5 |
| Rate differential on foreign earnings | (22) | (15) | 2 |
| Research and development benefit | (6) | | |
| State income taxes, net of federal benefit | 3 | 2 | 2 |
| Change in valuation allowance | (2) | 44 | 34 |
| Effective tax rate | 9% | 14% | 9% |

**(15) 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 segments are Consumer Products (comprised of the operating segments, consumer diagnostic products and vitamins and nutritional supplements), Professional Diagnostic Products, and Corporate and Other.

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. EBITDA is presented below because the Company believes that it is a useful indicator of its performance and ability to meet debt service and capital expenditure requirements. It allows investors and management to evaluate and compare the Company's operating results from continuing operations from period to period in a meaningful and consistent manner in addition to standard financial measurements under generally accepted accounting principles ("GAAP"). Management internally evaluates the performance of its businesses using EBITDA measures. EBITDA is not a measurement of financial performance under GAAP and should not be considered as an alternative to cash flow from operating activities or net income, as a measure of liquidity or as an indicator of operating performance or any measure of performance derived in accordance with GAAP. The Company's calculation of EBITDA may be different from the calculation used by other companies and, accordingly, comparability may be limited.

Revenues are attributed to geographic areas based on where the customer is located. Segment information for 2003, 2002, and 2001 are as follows:

| 2003 | Consumer Products | Professional Diagnostic Products | Corporate and Other | Total |
|---|---|---|---|---|
| | (restated) | | | (restated) |
| Net revenue to external customers | $ 206,514 | $ 90,198 | $ | $ 296,712 |
| EBITDA | 27,001 | 14,507 | (3,817) | 37,691 |
| Depreciation and amortization | 10,944 | 4,495 | 146 | 15,585 |
| Interest income | 220 | 58 | 765 | 1,043 |
| Interest expense | 1,280 | 2,628 | 5,803 | 9,711 |
| Provision for income taxes | 1,333 | 857 | (1,021) | 1,169 |
| Income (loss) from continuing operations | 13,664 | 6,585 | (7,980) | 12,269 |
| Stock-based compensation | 92 | 12 | 343 | 447 |
| Assets | 286,166 | 253,207 | 4,095 | 543,468 |
| Expenditures for property, plant and equipment | 7,408 | 3,166 | 561 | 11,135 |

| 2002 | Consumer Products | Professional Diagnostic Products | Corporate and Other | Total |
|---|---|---|---|---|
| | (restated) | (restated) | | (restated) |
| Net revenue to external customers | $ 172,499 | $ 34,305 | $ | $ 206,804 |
| EBITDA | 6,716 | 5,647 | (7,601) | 4,762 |
| Depreciation and amortization | 7,771 | 2,090 | 447 | 10,308 |
| Interest income | 287 | 29 | 1,107 | 1,423 |
| Interest expense | 5,249 | 1,702 | 8,118 | 15,069 |
| Provision for income taxes | 2,024 | 823 | (164) | 2,683 |
| Loss (income) from continuing operations | (8,041) | 1,061 | (14,895) | (21,875) |
| Charge related to asset impairment | 12,682 | | | 12,682 |
| Stock-based compensation | | | 10,625 | 10,625 |
| Assets | 220,223 | 107,698 | 29,334 | 357,255 |
| Expenditures for property, plant and equipment | 4,420 | 1,475 | 182 | 6,077 |

| 2001 | Consumer Products | Professional Diagnostic Products | Corporate and Other | Total |
|---|---|---|---|---|
| Net revenue to external customers | $ 36,677 | $ 10,591 | $ | $ 47,268 |
| EBITDA | 5,537 | (1,475) | (21,567) | (17,505) |
| Depreciation and amortization | 2,083 | 431 | 727 | 3,241 |
| Interest income | 89 | 11 | 285 | 385 |
| Interest expense | | | | |
| External | 1,117 | 205 | 703 | 2,025 |
| To IMT | 115 | | 154 | 269 |
| Total interest expense | 1,232 | 205 | 857 | 2,294 |
| Provision for income taxes | 1,966 | 18 | 150 | 2,134 |
| Income (loss) from continuing operations | 345 | (2,118) | (23,016) | (24,789) |
| Charge for in-process research and development | 6,980 | | | 6,980 |
| Stock-based compensation | | | 10,441 | 10,441 |
| Income from discontinued operations | | | 58 | 58 |
| Assets | 194,322 | 42,024 | 42,175 | 278,521 |
| Expenditures for property, plant and equipment | 2,372 | 394 | 828 | 3,594 |

| | 2003 (restated) | 2002 (restated) | 2001 |
|---|---|---|---|
| **Reconciliation of EBITDA to Income (Loss) from Continuing Operations** | | | |
| EBITDA | $ 37,691 | $ 4,762 | $ (17,505) |
| Depreciation and amortization expense | (15,585) | (10,308) | (3,241) |
| Interest expense, net of interest income | (8,668) | (13,646) | (1,909) |
| Income taxes | (1,169) | (2,683) | (2,134) |
| Income (loss) from continuing operations | $ 12,269 | $ (21,875) | $ (24,789) |

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

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

| | 2003 (restated) | 2002 (restated) | 2001 |
|---|---|---|---|
| **Revenue by Geographic Area** | | | |
| United States | $ 189,558 | $ 110,539 | $ 33,269 |
| Europe | 71,099 | 69,373 | 6,800 |
| Other | 36,055 | 26,892 | 7,199 |
| | $ 296,712 | $ 206,804 | $ 47,268 |

| | December 31, | |
|---|---|---|
| | 2003 | 2002 |
| **Long-lived Tangible Assets by Geographic Area** | | |
| United States | $ 28,458 | $ 23,272 |
| United Kingdom | 22,981 | 18,333 |
| Ireland | 3,557 | 3,194 |
| Other | 2,003 | 1,230 |
| | $ 56,999 | $ 46,029 |

**(16) 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 during 2001, through November 21, 2001, the date of split-off and merger, which it believes approximates arm's-length costs.

The charges by IMT to IMI, which are included in the respective captions in the accompanying consolidated statement of operations for 2001, are made up of the following:

| | |
|---|---|
| Cost of sales | $ 208 |
| Research and development | 23 |
| Sales and marketing | 1,365 |
| General and administrative | 1,437 |
| | $ 3,033 |

*(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 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 during 2001.

At December 31, 2000, the Company's Irish subsidiary, CDIL, had a note payable balance plus accrued interest totaling approximately $2,208 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 $183 during 2001.

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 $10,369, 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 $152, $1,910 and $181 during 2003, 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 and $1,059 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 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 statement of operations for 2001 include income from discontinued operations, through November 21, 2001, the date of the split-off and merger, as follows:

| | |
|---|---|
| Net product sales | $ 30,749 |
| Cost of sales | 22,606 |
| Gross profit | 8,143 |
| Operating expenses | 6,634 |
| Operating income | 1,509 |
| Other expenses, net | (689) |
| Income before income taxes | 820 |
| Provision for income taxes | 762 |
| Net income from discontinued operations | $ 58 |

**(17) 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 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, 2001 | $ 1,742 | $ 10,590 | $ (9,737) | $ 2,595 |
| Year ended December 31, 2002 (restated) | 2,595 | 20,470 | (15,527) | 7,538 |
| Year ended December 31, 2003 (restated)[1] | 7,538 | 19,617 | (19,663) | 7,492 |

(1) The amount charged against reserves for the year ended December 31, 2003 and the accounts receivable reserve balance as of December 31, 2003 have been corrected to reflect an error in the previous presentation of such amounts. This error involved the summarization of amounts for disclosure purposes only and does not impact reported consolidated results of operations or financial position.

In connection with its acquisitions of the Unipath business, IMN and Ostex, the Company recorded restructuring costs as part of the respective aggregate purchase prices in accordance with EITF Issue No. 95-3. The following table sets forth the aggregate restructuring costs and balances recorded in connection with the restructuring activities of the acquired businesses:

| | Balance at Beginning of Period | Costs Included in Purchase Price | Amounts Paid | Balance at End of Period |
|---|---|---|---|---|
| Year ended December 31, 2001 | $ | $ 2,340 | $ | $ 2,340 |
| Year ended December 31, 2002 | 2,340 | 3,406 | (3,474) | 2,272 |
| Year ended December 31, 2003 | 2,272 | 3,632 | (1,952) | 3,952 |

**(18) Guarantor Financial Information**

The Company issued $150,000 in Bonds to qualified institutional investors in reliance on Rule 144A under the Securities Act of 1933, as amended (the "Securities Act") and outside the United States in compliance with Regulation S of the Securities Act (Note 6(h)). The Company's payment obligations under the Bonds are guaranteed by certain of the Company's domestic subsidiaries (the "Guarantor Subsidiaries"). The guarantee is full and unconditional. Separate financial statements of the Guarantor Subsidiaries are not presented because the Company's management has determined that they would not be material to investors in the Bonds. The following supplemental financial information sets forth, on a consolidating basis, the statements of operations and cash flows for each of the three years in the period ended December 31, 2003 and the balance sheets as of December 31, 2003 and 2002 for the Company (the "Issuer"), the Guarantor Subsidiaries and the Company's other subsidiaries (the "Non-Guarantor Subsidiaries"). The supplemental financial information reflects the investments of the Company and the Guarantor Subsidiaries in the Guarantor and Non-Guarantor Subsidiaries using the equity method of accounting.

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

The Company's 2001 financial statements were audited by Arthur Andersen LLP who has ceased operations. Accordingly, the 2001 condensed consolidating financial information that follows is presented as unaudited upon the reliance of the SEC staff's guidance given in staff speech during the American Institute of Certified Public Accountants' Annual National Conference on Current SEC Developments in December 2003.

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**
**CONSOLIDATING STATEMENT OF OPERATIONS**
**For the Year Ended December 31, 2003**
**(restated)**

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| Net product sales | $ 22,717 | $ 111,264 | $ 196,268 | $ (43,265) | $ 286,984 |
| License revenue | | 401 | 9,327 | | 9,728 |
| **Net Revenue** | 22,717 | 111,665 | 205,595 | (43,265) | 296,712 |
| Cost of sales | 19,964 | 70,158 | 119,996 | (41,998) | 168,120 |
| **Gross profit** | 2,753 | 41,507 | 85,599 | (1,267) | 128,592 |
| Operating expenses: | | | | | |
| Research and development | 486 | 1,652 | 22,142 | | 24,280 |
| Sales and marketing | 2,062 | 22,141 | 27,502 | | 51,705 |
| General and administrative | 7,397 | 6,906 | 21,149 | | 35,452 |
| Stock-based compensation | 447 | | | | 447 |
| Total operating expenses | 10,392 | 30,699 | 70,793 | | 111,884 |
| **Operating (loss) income** | (7,639) | 10,808 | 14,806 | (1,267) | 16,708 |
| Equity in earnings (losses) of subsidiaries, net of tax | 18,431 | | | (18,431) | |
| Interest expense, including amortization of discounts (Note 6) | (3,711) | (2,518) | (4,560) | 1,078 | (9,711) |
| Other income (expense), net | 5,239 | 202 | 2,078 | (1,078) | 6,441 |
| **Income (loss) before income taxes** | 12,320 | 8,492 | 12,324 | (19,698) | 13,438 |
| Provision for income taxes | 51 | 777 | 185 | 156 | 1,169 |
| **Net income (loss)** | $ 12,269 | $ 7,715 | $ 12,139 | $ (19,854) | $ 12,269 |



**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**
**CONSOLIDATING STATEMENT OF OPERATIONS**
**For the Year Ended December 31, 2002**
**(restated)**

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| Net product sales | $ 22,639 | $ 47,683 | $ 164,590 | $ (34,513) | $ 200,399 |
| License revenue | | | 6,405 | | 6,405 |
| **Net Revenue** | 22,639 | 47,683 | 170,995 | (34,513) | 206,804 |

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| Cost of sales | 18,616 | 28,453 | 99,362 | (31,778) | 114,653 |
| **Gross profit** | 4,023 | 19,230 | 71,633 | (2,735) | 92,151 |
| Operating expenses: | | | | | |
| Research and development | 1,074 | 116 | 13,281 | | 14,471 |
| Sales and marketing | 2,229 | 13,586 | 23,729 | | 39,544 |
| General and administrative | 6,269 | 2,921 | 18,876 | | 28,066 |
| Charge related to asset impairment (Noted 5) | | 12,682 | | | 12,682 |
| Stock-based compensation (Note 12(c)) | 10,625 | | | | 10,625 |
| Total operating expenses | 20,197 | 29,305 | 55,886 | | 105,388 |
| **Operating (loss) income** | (16,174) | (10,075) | 15,747 | (2,735) | (13,237) |
| Equity in (losses) earnings of subsidiaries, net of tax | (21,062) | | | 21,062 | |
| Interest expense, including amortization of discounts (Note 6) | (8,039) | (194) | (7,244) | 408 | (15,069) |
| Other income (expense), net | 11,088 | 120 | (1,686) | (408) | 9,114 |
| **(Loss) income before income taxes** | (34,187) | (10,149) | 6,817 | 18,327 | (19,192) |
| (Benefit) provision for income taxes | (164) | 325 | 2,551 | (29) | 2,683 |
| **(Loss) income before cumulative effect of a change in accounting principle** | (34,023) | (10,474) | 4,266 | 18,356 | (21,875) |
| Cumulative effect of a change in accounting principle (Note 5) | | (12,148) | | | (12,148) |
| **Net (loss) income** | $ (34,023) | $ (22,622) | $ 4,266 | $ 18,356 | $ (34,023) |



**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**
**CONSOLIDATING STATEMENT OF OPERATIONS**
**For the Year Ended December 31, 2001**
**(unaudited)**

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| Net product sales | $ 1,836 | $ 31,390 | $ 23,332 | $ (9,290) | $ 47,268 |
| License revenue | | | | | |
| **Net Revenue** | 1,836 | 31,390 | 23,332 | (9,290) | 47,268 |
| Cost of sales | 1,752 | 20,463 | 13,317 | (8,870) | 26,662 |
| **Gross profit** | 84 | 10,927 | 10,015 | (420) | 20,606 |
| Operating expenses: | | | | | |
| | | | 6,980 | | 6,980 |

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| Purchased in-process research and development (Note 4(f)) | | | | | |
| Research and development | 12 | | 1,798 | | 1,810 |
| Sales and marketing | 362 | 3,920 | 3,736 | | 8,018 |
| General and administrative | 4,675 | 3,900 | 3,127 | | 11,702 |
| Stock-based compensation (Notes 1 and 12(c)) | 10,441 | | | | 10,441 |
| Total operating expenses | 15,490 | 7,820 | 15,641 | | 38,951 |
| **Operating (loss) income** | (15,406) | 3,107 | (5,626) | (420) | (18,345) |
| Equity in (losses) earnings of subsidiaries, net of tax | (8,896) | | | 8,896 | |
| Interest expense, including amortization of discounts (Note 6) | (565) | (1,187) | (543) | 1 | (2,294) |
| Other income (expense), net | 286 | 79 | (2,380) | (1) | (2,016) |
| **(Loss) income from continuing operations before income taxes** | (24,581) | 1,999 | (8,549) | 8,476 | (22,655) |
| Provision for income taxes | 150 | 1,951 | 33 | | 2,134 |
| **(Loss) income from continuing operations** | (24,731) | 48 | (8,582) | 8,476 | (24,789) |
| Income (loss) from discontinued operations, net of taxes (Note 16(d)) | | 310 | (252) | | 58 |
| **Net (loss) income** | $ (24,731) | $ 358 | $ (8,834) | $ 8,476 | $ (24,731) |



**CONSOLIDATING BALANCE SHEET**
**December 31, 2003**

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| **ASSETS** | | | | | |
| **Current Assets:** | | | | | |
| Cash and cash equivalents | $ 1,708 | $ 11,058 | $ 11,856 | $ | $ 24,622 |
| Accounts receivable, net of allowances | 3,915 | 29,505 | 21,998 | | 55,418 |
| Inventory | 4,463 | 19,737 | 28,980 | (6,137) | 47,043 |
| Deferred tax assets | | | 1,178 | | 1,178 |
| Prepaid expenses and other current assets | 1,365 | 1,507 | 7,727 | | 10,599 |
| Intercompany receivables | 6,073 | 5,114 | 8,911 | (20,098) | |
| **Total current assets** | 17,524 | 66,921 | 80,650 | (26,235) | 138,860 |
| Property, plant and equipment, net | 1,199 | 9,631 | 46,169 | | 56,999 |
| Goodwill | 48,704 | 81,907 | 103,181 | | 233,792 |

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| Trademarks and trade name with indefinite lives | | 9,092 | 29,027 | | 38,119 |
| Core technology and patents, net | 8,193 | 293 | 27,937 | | 36,423 |
| Other intangible assets, net | 6,437 | 14,198 | 7,108 | | 27,743 |
| Deferred financing costs, net, and other assets | 2,015 | 4,150 | 1,292 | | 7,457 |
| Deferred tax assets | 621 | 1,132 | 2,322 | | 4,075 |
| Investment in subsidiaries | 207,106 | | | (207,106) | |
| Intercompany notes receivable | 120,918 | 94,208 | | (215,126) | |
| **Total assets** | $ 412,717 | $ 281,532 | $ 297,686 | $ (448,467) | $ 543,468 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | | | | |
| **Current liabilities:** | | | | | |
| Current portion of long-term debt | $ | $ | $ 14,055 | $ | $ 14,055 |
| Current portion of capital lease obligations | | 18 | 439 | | 457 |
| Accounts payable | 4,448 | 11,431 | 22,127 | | 38,006 |
| Accrued expenses and other current liabilities | 8,641 | 14,879 | 17,602 | | 41,122 |
| Intercompany payables | 6,512 | 8,036 | 5,555 | (20,103) | |
| **Total current liabilities** | 19,601 | 34,364 | 59,778 | (20,103) | 93,640 |
| **Long-term liabilities:** | | | | | |
| Long-term debt | 34,056 | 91,974 | 33,808 | | 159,838 |
| Capital lease obligations | | 20 | 1,811 | | 1,831 |
| Deferred tax liabilities | | 1,752 | 7,366 | | 9,118 |
| Other liabilities | | | 3,307 | | 3,307 |
| Intercompany notes payable | 83,326 | 57,186 | 74,611 | (215,123) | |
| **Total long-term liabilities** | 117,382 | 150,932 | 120,903 | (215,123) | 174,094 |
| **Series A redeemable convertible preferred stock** | 6,185 | | | | 6,185 |
| **Stockholders' equity** | 269,549 | 96,236 | 117,005 | (213,241) | 269,549 |
| **Total liabilities and stockholders' equity** | $ 412,717 | $ 281,532 | $ 297,686 | $ (448,467) | $ 543,468 |



**CONSOLIDATING BALANCE SHEET**
**December 31, 2002**
**(restated)**

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| **ASSETS** | | | | | |
| **Current assets:** | | | | | |
| Cash and cash equivalents | $ 3,004 | $ 16,069 | $ 11,595 | $ | $ 30,668 |
| Accounts receivable, net of allowances | 4,277 | 11,925 | 20,702 | | 36,904 |
| Inventory | 4,759 | 11,285 | 26,055 | (5,056) | 37,043 |
| Deferred tax assets | | | 2,137 | | 2,137 |
| Prepaid expenses and other current assets | 2,087 | 1,501 | 2,868 | | 6,456 |
| Intercompany receivables | 12,482 | 20,176 | 14,368 | (47,026) | |
| **Total current assets** | 26,609 | 60,956 | 77,725 | (52,082) | 113,208 |
| Property, plant and equipment, net | 1,005 | 2,703 | 42,321 | | 46,029 |
| Goodwill | 18,106 | 35,362 | 55,447 | | 108,915 |
| Trademarks and trade name with indefinite lives | | 6,020 | 25,699 | | 31,719 |
| Core technology and patents, net | 3,157 | | 22,648 | | 25,805 |
| Other intangible assets, net | | 14,784 | 7,590 | | 22,374 |
| Deferred financing costs, net, and other assets | 2,154 | 787 | 1,967 | | 4,908 |
| Deferred tax assets | 223 | 2,691 | 1,227 | 156 | 4,297 |
| Investment in subsidiaries | 168,831 | | | (168,831) | |
| Intercompany notes receivable | 13,380 | | 43,263 | (56,643) | |
| **Total assets** | $ 233,465 | $ 123,303 | $ 277,887 | $ (277,400) | $ 357,255 |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | | | | |
| **Current liabilities:** | | | | | |
| Current portion of long-term debt | $ | $ 3,750 | $ 13,450 | $ | $ 17,200 |
| Current portion of capital lease obligations | | | 642 | | 642 |
| Accounts payable | 3,857 | 6,111 | 19,261 | | 29,229 |
| Accrued expenses and other current liabilities | 5,404 | 13,173 | 19,875 | | 38,452 |
| Intercompany payables | 17,465 | 8,775 | 9,009 | (35,249) | |
| **Total current liabilities** | 26,726 | 31,809 | 62,237 | (35,249) | 85,523 |
| **Long-term liabilities:** | | | | | |
| Long-term debt | 33,856 | 16,250 | 34,427 | | 84,533 |
| Capital lease obligations | | | 2,238 | | 2,238 |
| Deferred tax liabilities | | 2,915 | 6,450 | | 9,365 |
| Other liabilities | 1,223 | | 2,713 | | 3,936 |
| Intercompany notes payable | | | 68,419 | (68,419) | |
| **Total long-term liabilities** | 35,079 | 19,165 | 114,247 | (68,419) | 100,072 |
| | 9,051 | | | | 9,051 |

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| **Series A redeemable convertible preferred stock** | | | | | |
| **Stockholders' equity** | 162,609 | 72,329 | 101,403 | (173,732) | 162,609 |
| **Total liabilities and stockholders' equity** | $ 233,465 | $ 123,303 | $ 277,887 | $ (277,400) | $ 357,255 |



**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**
**CONSOLIDATING STATEMENT OF CASH FLOWS**
**For the Year Ended December 31, 2003**
**(restated)**

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| **Cash Flows from Operating Activities:** | | | | | |
| Net income (loss) | $ 12,269 | $ 7,715 | $ 12,139 | $ (19,854) | $ 12,269 |
| Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities: | | | | | |
| Equity in (earnings) losses of subsidiaries, net of tax | (18,431) | | | 18,431 | |
| Interest expense related to amortization of noncash original issue discount, noncash beneficial conversion feature and deferred financing costs | 454 | 504 | 607 | | 1,565 |
| Noncash gain related to interest rate swap agreement | (528) | | | | (528) |
| Noncash stock-based compensation expense | 447 | | | | 447 |
| Depreciation and amortization | 958 | 3,266 | 11,361 | | 15,585 |
| Deferred income taxes | (397) | (1,534) | 727 | 157 | (1,047) |
| Changes in assets and liabilities, net of acquisitions: | | | | | |
| Accounts receivable, net | 749 | (9,462) | (450) | (429) | (9,592) |
| Inventory | 295 | (1,930) | (1,685) | 1,266 | (2,054) |
| Prepaid expenses and other current assets | (336) | 279 | (4,045) | | (4,102) |
| Intercompany payable (receivable) | 14,251 | (39,188) | 25,435 | (498) | |
| Accounts payable | (737) | 3,851 | 1,667 | 1,934 | 6,715 |
| Accrued expenses and other current liabilities | 3,885 | (6,038) | (7,304) | | (9,457) |
| **Net cash provided by (used in) operating activities** | 12,879 | (42,537) | 38,452 | 1,007 | 9,801 |

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**
**CONSOLIDATING STATEMENT OF CASH FLOWS (continued)**
**For the Year Ended December 31, 2003**
**(restated)**

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| **Cash Flows from Investing Activities:** | | | | | |
| Purchases of property, plant and equipment | (497) | (2,355) | (8,283) | | (11,135) |
| Proceeds from sale of property, plant and equipment | | 72 | 80 | | 152 |
| Cash paid to acquire certain assets from Abbott | | (26,855) | (29,092) | | (55,947) |
| Cash paid to acquire ABI, net of cash received | (14,043) | 1 | | | (14,042) |
| Cash paid to acquire Ostex, Inc, net of cash received | (1,530) | (373) | | | (1,903) |
| Cash paid to acquire Wampole Divison of MedPoint Inc | (1,460) | | | | (1,460) |
| Cash paid to acquire IVC Industries, net of cash received | (535) | | | | (535) |
| Cash paid to acquire Unipath, net of cash received | | | (649) | | (649) |
| Cash paid to acquire other businesses and intellectual property | | | (4,007) | | (4,007) |
| Decrease (increase) in other assets | 719 | (506) | 183 | | 396 |
| **Net cash used in investing activities** | (17,346) | (30,016) | (41,768) | | (89,130) |
| **Cash Flows from Financing Activities:** | | | | | |
| Cash paid for financing costs | (832) | (3,652) | (49) | | (4,533) |
| Proceeds from issuance of common stock, net of issuance costs | 4,003 | | | | 4,003 |
| Net proceeds from line of credit | | 16,899 | 2,432 | | 19,331 |
| Net proceeds from borrowings under notes payable | | 57,575 | 46 | | 57,621 |
| Repayments of notes payable | | (3,271) | (2,514) | | (5,785) |
| Principal payments of capital lease obligations | | (9) | (642) | | (651) |
| **Net cash provided by (used in) financing activities** | 3,171 | 67,542 | (727) | | 69,986 |
| Foreign exchange effect on cash and cash equivalents | | | 4,304 | (1,007) | 3,297 |
| **Net (decrease) increase in cash and cash equivalents** | (1,296) | (5,011) | 261 | | (6,046) |
| **Cash and cash equivalents, beginning of year** | 3,004 | 16,069 | 11,595 | | 30,668 |
| **Cash and cash equivalents, end of year** | $ 1,708 | $ 11,058 | $ 11,856 | $ | $ 24,622 |

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**
**CONSOLIDATING STATEMENT OF CASH FLOWS**
**For the Year Ended December 31, 2002**
**(restated)**

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| **Cash Flows from Operating Activities:** | | | | | |
| Net (loss) income | $ (34,023) | $ (22,622) | $ 4,266 | $ 18,356 | $ (34,023) |
| Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities: | | | | | |
| Equity in losses (earnings) of subsidiaries, net of tax | 21,062 | | | (21,062) | |
| Interest expense related to amortization of noncash original issue discount, noncash beneficial conversion feature and deferred financing costs | 4,780 | 34 | 2,685 | | 7,499 |
| Noncash charge related to interest rate swap agreement | 1,223 | | | | 1,223 |
| Noncash stock-based compensation expense | 10,625 | | | | 10,625 |
| Noncash beneficial conversion feature related to early extinguishment of debt | (9,600) | | | | (9,600) |
| Noncash charge related to asset impairment and cumulative effect of a change in accounting principle | | 24,830 | | | 24,830 |
| Depreciation and amortization | 570 | 924 | 8,814 | | 10,308 |
| Deferred income taxes | | | 26 | | 26 |
| Other noncash items | | | 354 | | 354 |
| Changes in assets and liabilities, net of acquisitions: | | | | | |
| Accounts receivable, net | (5,232) | 5,665 | 794 | | 1,227 |
| Inventory | (3,500) | (807) | 1 | 2,216 | (2,090) |
| Prepaid expenses and other current assets | 1,348 | (111) | (769) | | 468 |
| Intercompany (receivable) payable | (2,762) | (17,564) | 4,462 | 15,864 | |
| Accounts payable | 3,185 | 1,683 | 3,979 | | 8,847 |
| Accrued expenses and other current liabilities | (11,489) | (627) | 1,069 | 489 | (10,558) |
| **Net cash (used in) provided by operating activities** | (23,813) | (8,595) | 25,681 | 15,863 | 9,136 |



**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**
**CONSOLIDATING STATEMENT OF CASH FLOWS (continued)**
**For the Year Ended December 31, 2002**
**(restated)**

| Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| **Cash Flows from Investing Activities:** | | | | | |
| Purchases of property, plant and equipment | (189) | (377) | (5,511) | | (6,077) |
| Proceeds from sale of property, plant and equipment | | 22 | 1,523 | | 1,545 |
| Cash paid for purchase of the Wampole Division of MedPointe Inc. | (66,708) | | (3,900) | | (70,608) |
| Cash paid for purchase of IVC Industries, Inc., net of cash acquired | (11,488) | | 4,376 | | (7,112) |
| Cash paid for purchase of Unipath business, net of cash acquired | (1,979) | | (853) | | (2,832) |
| Loan to Ostex International, Inc | (1,000) | | | | (1,000) |
| (Increase) decrease in other assets | (564) | 4 | | | (560) |
| Net cash used in investing activities | (81,928) | (351) | (4,365) | | (86,644) |
| **Cash Flows from Financing Activities:** | | | | | |
| Cash paid for financing costs | (1,207) | (814) | (1,954) | | (3,975) |
| Proceeds from issuance of common stock, net of issuance costs | 35,322 | | | | 35,322 |
| Proceeds from issuance of preferred stock, net of issuance costs | 20,567 | | | | 20,567 |
| Net proceeds received under revolving line of credit | | | 2,649 | | 2,649 |
| Net proceeds from borrowings under notes payable | 35,000 | 16,250 | 33,171 | | 84,421 |
| Repayments of notes payable | (20,000) | 3,750 | (65,990) | | (82,240) |
| Principal payments of capital lease obligations | | | (494) | | (494) |
| **Net cash provided by (used in) financing activities** | 69,682 | 19,186 | (32,618) | | 56,250 |
| Foreign exchange effect on cash and cash equivalents | | | 15,765 | (15,863) | (98) |
| **Net (decrease) increase in cash and cash equivalents** | (36,059) | 10,240 | 4,463 | | (21,356) |
| **Cash and cash equivalents, beginning of year** | 39,063 | 5,829 | 7,132 | | 52,024 |
| **Cash and cash equivalents, end of year** | $ 3,004 | $ 16,069 | $ 11,595 | $ | $ 30,668 |



**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**
**CONSOLIDATING STATEMENT OF CASH FLOWS**
**For the Year Ended December 31, 2001**
**(unaudited)**

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| **Cash Flows from Operating Activities:** | | | | | |

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| Net (loss) income | $ (24,731) | $ 358 | $ (8,834) | $ 8,476 | $ (24,731) |
| Net (income) loss from discontinued operations | | (310) | 252 | | (58) |
| Net (loss) income, excluding discontinued operations | (24,731) | 48 | (8,582) | 8,476 | (24,789) |
| Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities: | | | | | |
| Equity in losses (earnings) of subsidiaries, net of tax | 8,896 | | | (8,896) | |
| Interest expense related to amortization of noncash original issue discount, noncash beneficial conversion feature and deferred financing costs | 431 | 403 | 5 | | 839 |
| Noncash stock-based compensation expense | 10,441 | | | | 10,441 |
| Charge for in-process research and development | | | 6,980 | | 6,980 |
| Depreciation and amortization | 634 | 1,593 | 1,014 | | 3,241 |
| Deferred income taxes | | 419 | | | 419 |
| Other noncash items | | | 546 | | 546 |
| Capital contribution from Inverness Medical Technology, Inc related to income taxes for Inverness Medical, Inc | | 987 | | | 987 |
| Changes in assets and liabilities, net of acquisitions: | | | | | |
| Accounts receivable, net | | 1,942 | 357 | (543) | 1,756 |
| Inventory | | 399 | (1,585) | 963 | (223) |
| Prepaid expenses and other current assets | (2,086) | (832) | 1,101 | | (1,817) |
| Intercompany (receivable) payable | (81,453) | (596) | 86,167 | (4,118) | |
| Accounts payable | 80 | (116) | (700) | | (736) |
| Accrued expenses and other current liabilities | 13,351 | 2,372 | (628) | | 15,095 |
| Due to Inverness Medical Technology, Inc. & affililates | | | 2,649 | | 2,649 |
| **Net cash (used in) provided by operating activities** | (74,437) | 6,619 | 87,324 | (4,118) | 15,388 |
| **Net cash used in assets of discontinued operations** | | (506) | (664) | | (1,170) |



**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**
**CONSOLIDATING STATEMENT OF CASH FLOWS (continued)**
**For the Year Ended December 31, 2001**
**(unaudited)**

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| **Cash Flows from Investing Activities:** | | | | | |
| Purchases of property, plant and equipment | (780) | (804) | (2,010) | | (3,594) |
| Proceeds from sale of property, plant and equipment | | | 141 | | 141 |
| Cash paid to acquire Unipath, net of cash received | (12,895) | 1,989 | (135,248) | | (146,154) |
| (Increase) decrease in other assets | (187) | 341 | (25) | | 129 |
| **Net cash (used in) provided by investing activities** | (13,862) | 1,526 | (137,142) | | (149,478) |
| **Cash Flows from Financing Activities:** | | | | | |
| Cash paid for financing costs | (33) | | (2,163) | | (2,196) |
| Proceeds from issuance of common stock, net of issuance costs | 568 | | | | 568 |
| Net proceeds from borrowings under notes payable | 20,000 | | 62,552 | | 82,552 |
| Repayments of notes payable | | (3,513) | (794) | | (4,307) |
| Net proceeds from sales of preferred stock | 59,798 | | | | 59,798 |
| Contribution from Inverness Medical Technology, Inc. | 47,029 | (26) | 656 | | 47,659 |
| **Net cash provided by (used in) financing activities** | 127,362 | (3,539) | 60,251 | | 184,074 |
| Foreign exchange effect on cash and cash equivalents | | | (3,980) | 4,118 | 138 |
| **Net increase in cash and cash equivalents** | 39,063 | 4,100 | 5,789 | | 48,952 |
| **Cash and cash equivalents, beginning of year** | | 1,729 | 1,343 | | 3,072 |
| **Cash and cash equivalents, end of year** | $ 39,063 | $ 5,829 | $ 7,132 | $ | $ 52,024 |



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