INVERNESS MEDICAL INNOVATIONS INC
Form 10-K
March 16, 2005

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

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

(Mark One)

ý **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2004

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, 2004 (the last business day of the registrant's most recently completed second fiscal quarter) was $359,073,385.50. 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 15, 2005, the registrant had 20,798,141 shares of common stock, par value $0.001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement to be filed with the Securities and Exchange Commission on or prior to April 30, 2005 are incorporated by reference into Part III of this Form 10-K.

PART I

This annual report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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. We caution investors that all such forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from any projected results or expectations that we discuss in this report. You should therefore carefully review the risk factors and uncertainties 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 40 and 56, respectively, in this report, as well as those factors identified from time to time in our periodic filings with the Securities and Exchange Commission. We undertake no obligation to update any forward-looking statements.

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.

ITEM 1. BUSINESS

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 company, Inverness Medical Innovations, Inc., a Delaware corporation, was formed to acquire the women's health, nutritional supplements and professional diagnostics businesses of its predecessor, Inverness Medical Technology, Inc., through a split-off and merger transaction, which occurred in November 2001. We became an independent, publicly traded company immediately after the split-off and our common stock is listed on the American Stock Exchange under the symbol "IMA." Since the split-off, we have grown our businesses by leveraging our strong intellectual property portfolio and making selected strategic acquisitions. We are presently exploring new opportunities for our proprietary lateral flow, electrochemical and other technologies in a variety of professional diagnostic and consumer-oriented applications including immuno-diagnostics with a focus on women's health, cardiology and infectious disease.

Our principal executive offices are located at 51 Sawyer Road, Suite 200, Waltham, Massachusetts 02453 and our telephone number is (781) 647-3900. 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 Securities and Exchange Commission. These reports may be accessed through our website's investor information page.

RECENT DEVELOPMENTS

On February 8, 2005, we agreed to acquire Binax, Inc., a developer, manufacturer and distributor of rapid diagnostic products for infectious disease testing, primarily related to the respiratory system, in exchange for 1,433,333 shares of our common stock and $8.6 million in cash. We also agreed to pay the Binax shareholders up to $11 million in cash if Binax meets certain new product development performance objectives during the next five years. Binax had 2004 revenues of approximately $20 million. The acquisition is expected to close during the second half of March 2005.

On February 15, 2005, we agreed to acquire Ischemia Technologies, Inc. for approximately $22.4 million of our common stock, subject to adjustment. Using patented technology which we will acquire, Ischemia developed and currently sells the only FDA-cleared in vitro diagnostic test specifically targeted at cardiac ischemia. Ischemia had 2004 revenues of less than $1 million. The acquisition is expected to close on or about March 16, 2005.

On February 25, 2005, we entered into a co-development agreement with ITI Scotland Limited, whereby ITI Scotland agreed to provide us with approximately $57 million, over three years to partially fund research and development programs focused on identifying novel biomarkers and near-patient and home use tests for cardiovascular and other diseases. We agreed to invest $72 million of our planned research and development spending in these programs over the next three years. Through our subsidiary, Stirling Medical Innovations Limited, we intend to establish a new research center in Stirling, Scotland where we will consolidate many of our existing cardiology programs and ultimately commercialize products arising from the programs.

SEGMENTS

Our major reportable segments are consumer diagnostic products, vitamins and nutritional supplements and professional diagnostic products. Below are discussions of each of these 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.

Products

Consumer Diagnostic Products. 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. Our pregnancy and fertility/ovulation tests display visual results in approximately one minute or three minutes depending on the product. 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, which are generally disposable stick tests similar to pregnancy stick tests, are easy to use and are widely accepted for home use by professional fertility care providers and the general public. 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.

To serve these markets we offer premium branded products, value branded products and private label diagnostic products. Our premium branded Clearblue home pregnancy and fertility/ovulation prediction tests are global leaders in terms of both sales and technology. We also offer Clearblue Easy Digital pregnancy and fertility/ovulation prediction tests. Our Clearblue Easy Digital pregnancy test was launched in June 2003 as the first consumer pregnancy test to display test results in words, as opposed to displaying results with colored lines that require interpretation. To supplement our premium line of traditional Clearblue fertility/ovulation disposable stick tests, we also offer the Clearblue Easy Fertility Monitor, the only hormone-based reusable monitoring device available for home use to assist women attempting to conceive. This product, which is sold primarily in the United States and Canada, 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.

Our Fact plus and Accu-Clear branded pregnancy and fertility/ovulation prediction products are marketed to value-oriented consumers. We are also a major U.S. supplier of private label home pregnancy detection and fertility/ovulation prediction products and we currently supply Pfizer with both the digital and non-digital versions of its e.p.t brand pregnancy tests. 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.

Vitamins and Nutritional Supplements. We also market a wide variety of vitamins and nutritional supplements primarily within the United States. Most growth in this market 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.

Our subsidiary, 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.

Professional Diagnostic Products. Professional diagnostic products are 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. Our current professional diagnostic products consist primarily of laboratory and point-of-care tests in the areas of women's health, infectious disease, cardiovascular disease and drugs of abuse. The market for rapid diagnostic products consists primarily of small and medium sized, non-centralized laboratories and testing locations such as physician office laboratories, specialist mobile clinics, emergency rooms 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 many other segments of the immunoassay market due to the increasing incidence of certain diseases or groups of diseases, including viral hepatitis, respiratory syncytial virus (RSV), influenza, tuberculosis, acquired immunodeficiency syndrome and other sexually transmitted diseases. We also believe that, in general, 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.

In the United States, our professional diagnostic products, which include our Signify and Clearview brands, are generally sold under our Wampole label, and we also distribute products on behalf of third

parties. Outside of the United States, we market our Clearview, SureStep and TestPack products. 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, fecal occult blood, D-dimer, RSV, Influenza A/B 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.

ELISA Products. We offer over 70 enzyme linked immunosorbent assays (ELISA) tests for a wide variety of infectious and sexually transmitted diseases, as well as a full line of automated instrumentation for processing ELISA assays.

AtheNA Multi-Lyte Test System. We 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 AtheNA Multi-Lyte ANA test provides improved clinical sensitivity and comparable clinical specificity to ELISA in a labor saving, automated user-friendly format.

IFA/Serology Products. We also offer a line of indirect fluorescent antibody, or IFA, assays for over 20 viral, bacterial and autoimmune diseases and a full line of serology diagnostic products covering a broad range of disease categories. 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.

Methods of Distribution

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 such as Walgreens, CVS, Wal-Mart, Mitsui & Co UK, Schering Spa and Boots. 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 are value-oriented brands which are not currently advertised. Our consumer diagnostic products are marketed in the United States, the United Kingdom and Germany using our own sales managers and a network of sales representatives. In Australia, where we recently acquired Crystal Clear, the leading brand in that market, we distribute through a transitional arrangement with the seller. In other areas of the world, including Japan, Canada and the rest of Europe, our consumer diagnostic products are sold though distribution contracts with large consumer diagnostics companies. Private label and contract manufacturing arrangements accounted for 26% of our consumer diagnostics business' net product sales for 2004.

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 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 2004, based on net product sales, together accounted for almost 65% of our net product sales for this segment and one of them, Walgreens, accounted for approximately 11% of our net product sales on a consolidated basis. Our rights to the trademarks Stresstabs, Ferro-Sequels, Posture-D, Protegra,

ALLBEE and Z-BEC are limited to use in the United States, but we are not restricted from marketing the formulations sold under those brand names in other areas of the world.

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. In the United Kingdom, Germany and, since January 2005, France, we 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 distribute products for other parties, primarily in Germany, through our subsidiary, Viva Diagnostika GmbH.

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 serves as our U.S. distributor for the Signify product line until September 30, 2005, except to physician office laboratories currently served by PSS World Medical, Inc.. Outside the United States, Abbott distributes the TestPack and Signify product lines for us until March 31, 2005. We have already begun transferring distribution of these products to other third parties. Our TestPack products are not approved for sale, and are not sold, in the United States.

Manufacturing

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 are each ISO certified and registered with the United States Food and Drug Administration. In September 2004, we began manufacturing a small amount of product in China through a third party. In February 2005, we entered into a joint venture with this Chinese manufacturer and acquired controlling ownership of the manufacturing facility. We expect this manufacturing operation to expand considerably over the next few years. We use our Bedford facility to manufacture the diagnostic test portion of our Clearblue Easy Digital products, and the non-digital and digital e.p.t pregnancy tests for Pfizer. We purchase the electronic portion of our digital pregnancy and ovulation prediction 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.

Vitamins and Nutritional Supplements. We manufacture substantially all of our vitamin and nutritional products at IMN's facilities in Freehold and Irvington, New Jersey. IMN internally manufactures substantially all of its softgel requirements at the Irvington facility. Our Freehold facility manufactures in full compliance with Good Manufacturing Practices, or GMP, standards recently proposed by the FDA for the dietary supplement industry. Our Irvington facility manufactures to GMP standards applicable to drug makers and is registered with both the United States Drug Enforcement Agency, or the DEA, and the FDA.

Professional Diagnostic Products. Approximately 53% of the professional diagnostic products that we sell, based on net product sales for the fiscal year ended December 31, 2004 were manufactured by third parties. We manufacture the products we acquired through our acquisition of Applied Biotech, Inc., or ABI, as well as the Signify products that we acquired from Abbott Laboratories, at our facilities in San Diego, California. Most of our TestPack products that we acquired from Abbott in September 2003 continue to be manufactured by Abbott under a transitional arrangement. We expect to transition manufacturing of these products to our own facilities during 2005. Our Clearview diagnostic products are manufactured both at our facility in Bedford, England, and at ABI in San Diego, 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, with the rest being manufactured by a third-party.

Research and Development

A significant portion our budget for research and development currently is allocated to the development of cardiovascular disease management products, a market for which we do not currently offer products. 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 in Bedford, England, but we also conduct research and development at our facilities in Galway, San Diego, Yavne, and Farum, Denmark. We have also recently announced that we are establishing a cardiovascular research center in Stirling, Scotland using approximately $57 million in co-development funding to be provided by ITI Scotland Limited and at least $72 million of our own funds over three years. In addition, 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.

Foreign Operations

Our business relies heavily on our foreign operations. Four of our seven current manufacturing facilities are outside the United States, including our primary consumer diagnostic products manufacturing facilities in Bedford, England and Galway, Ireland. Approximately 40% of our net revenues were generated from outside of the United States during 2004. Our Clearblue products, pregnancy tests in particular, have historically been much stronger brands outside the United States, with 74% of our net product sales of Clearblue products coming from outside the United States during 2004. Our TestPack product line is sold exclusively outside the United States.

Competitive Conditions

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 with substantially greater resources than we have. 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. Our competitors for the sale of pregnancy test products worldwide include Church & Dwight, Pfizer, Acon Laboratories, Omega Pharma, Princeton BioMeditech, Arax, Rohto and Syntron Bioresearch, although we currently supply Pfizer with its pregnancy test products. Our competitors for the sale of fertility/ovulation prediction tests include Church & Dwight, 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.

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 Acon Laboratories. Some competitors in this market, such as Becton Dickinson are large companies with substantially greater resources than we have. Other competitors in some product segments, particularly drugs of abuse, are smaller yet aggressive companies. These competitors include ALFA, Syntron Bioresearch, Princeton BioMeditech and Genzyme Diagnostics. 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.

We believe that our dedication to research and development and our strong intellectual property portfolio, coupled with our advanced manufacturing expertise, diversified product positioning, global market presence and established distribution networks, provide us with a competitive advantage in the point-of-care markets in which we compete.

Patents and Proprietary Technology; Trademarks

We have 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 and most of our rapid membrane products for the point-of-care marketplaces that we serve. 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, 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. Our intellectual property portfolio consists of patents that we own and, in some cases, licenses to patents or other proprietary rights of third parties which may be limited in terms of field of use, transferability or may require royalty payments.

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, over $7.6 million during 2004, 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.

Finally, we believe that certain of our trademarks are valuable assets that are important to the marketing of both our consumer and professional products. Many of these trademarks have been registered with the United States Patent and Trademark Office or internationally, as appropriate.

The medical products industry, including the diagnostic testing industry, places considerable importance on obtaining and enforcing patent and trade secret protection for new technologies, products and processes. Trademark protection is an important factor in the success of certain of our consumer and professional diagnostic product lines. Our success therefore depends, in part, on our abilities to obtain and enforce the patents and trademark registrations necessary to protect our products, to preserve our trade secrets and to avoid or neutralize threats to our proprietary rights from third parties. We cannot, however, guarantee our success in enforcing or maintaining our patent rights; in obtaining future patents or licensed patents in a timely manner or at all; or as to the breadth or degree of protection that our patents or trademark registrations or other intellectual property rights might afford us. For more information regarding the risks associated with our reliance on intellectual property rights see the risk factors discussed on pages 51 through 52 of the section of this report entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations Certain Factors Affecting Future Results."

Government Regulation

Our research, development and clinical programs, as well as our manufacturing and marketing operations, are subject to extensive regulation in the United States and other countries. Most notably all of our products sold in the United States are subject to the Federal Food, Drug and Cosmetic Act, or the FDCA, as implemented and enforced by the U.S. Food and Drug Administration, or the FDA. All of our diagnostic products sold in the United States require FDA clearance to market under Section 510k of the FDCA, which may require pre-clinical and clinical trials. Foreign countries may require similar or more onerous approvals to manufacture or market these products. The marketing of our consumer diagnostic products is also subject to regulation by the U.S. Federal Trade Commission, or the FTC. In addition, we are required to meet regulatory requirements in countries outside the United States, which can change rapidly with relatively short notice.

In March 2005, our ABI subsidiary was informed by the FDA that, based on inspectional findings that included data integrity and design control issues, ABI has become subject to the FDA's Application Integrity Policy. As a result, the FDA will defer the review of any pending or future applications made by ABI until the FDA determines that ABI has resolved these issues. ABI currently has no applications pending. At this time ABI is not restricted with regard to introducing new tests outside of the United States, or from selling products in the United States based on any existing 510(k)s. It is our understanding that the FDA action applies only to ABI and does not otherwise restrict our ability, or the ability of our other subsidiaries, to submit applications to the FDA or commercialize products. However, the scope and the impact are uncertain, and may have a negative effect on our future sales and profits.

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 GMP standards 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.

Employees

As of March 1, 2005, we had a total of 1,680 full-time employees, of which 758 employees are located in the United States. In addition, we utilize the services of temporary and part-time employees, as well as a number of consultants specializing in areas such as research and development, risk management, regulatory compliance, strategic planning and marketing.

ITEM 2. DESCRIPTION OF PROPERTY

Our principal corporate administrative office, together with the administrative office for most of our United States operations, is housed in approximately 22,600 square feet of leased space located at 51 Sawyer Road, Waltham, Massachusetts. 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. We also manufacture products for both our consumer products segment and professional diagnostic products segment and conduct substantial research and development activity at the Bedford facility. We are currently using the Bedford facility pursuant to an agreement with Unilever entered into in connection with our acquisition of the Unipath business in 2001. Unilever currently leases this facility from a third party landlord. Pursuant to 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 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.

We also have manufacturing operations in Shanghai, China, Freehold, New Jersey, Irvington, New Jersey, San Diego, California, Galway, Ireland and Yavne, Israel. We currently manufacture a small amount of product for our consumer products business out of 13,000 square feet of space that we lease in Shanghai, China, though we expect our manufacturing volume at this facility to grow considerably over the next few years. We also manufacture both consumer and professional diagnostic products out of a 40,000 square foot facility that we lease in San Diego, California and out of a 40,000 square foot facility in Galway, Ireland. We own half of the Galway facility and lease the other half from a private developer. We also own a 160,000 square foot manufacturing facility in Freehold, New Jersey and lease a 35,000 square foot facility in Irvington, New Jersey. These New Jersey facilities manufacture our vitamin and nutritional supplement products. 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.

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), Canada (Boucherville), Denmark (Farum), Belgium (Sint-Niklaas), Germany (Cologne and Munich), France (Paris) and Sweden (Lund), and our Orgenics products are sold through small sales offices in France, Brazil and several other countries. We have also recently leased a small amount of office and lab space in Stirling, Scotland in connection with our recently announced research, development and exploitation arrangement. We expect to ultimately build and lease a much larger facility in Stirling from which we will conduct significant manufacturing and research and development activities.

ITEM 3. LEGAL PROCEEDINGS

Inverness Medical Switzerland GmbH, et al. v. Princeton Biomeditech Corporation

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 January 2004, our subsidiary, Inverness Medical Switzerland, GmbH (IMS), filed suit against Quidel Corporation in Germany 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 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. 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 to which we have a license, and that these patents are invalid and/or unenforceable. Quidel seeks injunctive relief and damages. 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 these 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. During May 2004, the Court held hearings regarding construction of the patents at issue and rejected various arguments made by Quidel in an effort to limit the scope of certain of our patents. Claim construction hearings regarding the Quidel patent and other remaining patents are ongoing. In September 2004, Quidel served a suit on Unipath Diagnostics GmbH and its directors in the District

Court of Mannheim, Germany, alleging infringement of the German equivalent of the Quidel patent. We have responded, denying liability, and the proceeding is ongoing. We intend to vigorously defend the Quidel claims and vigorously prosecute our infringement counterclaims and separate claims to enforce our 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. 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 our ongoing litigation against Acon Laboratories. These suits can be expensive and result in counterclaims challenging the validity of our patents and other rights.

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

No matters were submitted to a vote of our security holders during the fourth quarter of the year ended December 31, 2004.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY

Our common stock trades on the American Stock Exchange (AMEX) under the symbol "IMA." The following table sets forth the high and low sales prices of our common stock on AMEX for each quarter during fiscal 2004 and 2003.

	High	Low
Fiscal 2004		
Fourth Quarter	$ 25.50	$ 18.10
Third Quarter	$ 22.60	$ 14.75
Second Quarter	$ 22.00	$ 16.90
First Quarter	$ 25.00	$ 18.25
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

On March 10, 2005, there were 20,798,141 holders of record of our common stock.

We have never declared or paid any cash dividends on our common stock. We currently intend to retain earnings to support our growth strategy and do not anticipate paying cash dividends on our common stock in the foreseeable future. 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.

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, 2004 and should be read in conjunction with our consolidated financial statements and notes thereto included elsewhere in this annual report on Form 10-K.

The selected consolidated financial data as of December 31, 2004 and 2003 and for each of the three years in the period ended December 31, 2004 have been derived from our consolidated financial statements which are included elsewhere in this annual report on Form 10-K and were audited by BDO Seidman, LLP, independent registered public accounting firm. The selected consolidated financial data as of December 31, 2002 have been derived from our consolidated financial statements not included herein, which were audited by BDO Seidman, LLP. The selected consolidated financial data as of December 31, 2001 and 2000 and for each of the two years in the period ended December 31, 2001 have been derived from our consolidated financial statements not included herein, which were audited by Arthur Andersen LLP, independent public accountants.

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, Applied Biotech, Inc. in August 2003 and the Abbott rapid diagnostics business 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 restated our originally 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 originally been reported in other income, 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 originally 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 originally been corrected in the periods in which they had been identified rather than in the periods to which they related.

We further restated our previously issued consolidated financial statements as of and for the years ended December 31, 2003 and 2002 to correct an error in the calculation of the provisions for income taxes and the related deferred tax accounts. We should have reported gross, certain deferred tax liabilities associated with temporary differences related to differing tax and book bases of goodwill and

other intangible assets. As a result, we have recorded an additional valuation allowance against the deferred tax assets associated with certain net operating loss carry forwards. The correction of this error resulted in incremental non-cash provisions of income taxes in the amount of $1.9 million and $0.8 million in 2003 and 2002, respectively. In addition, we revised our purchase price allocation in connection with our acquisition of the Abbott business on September 30, 2003 to attribute $5.7 million to customer related intangible assets acquired in the acquisition. We have also recorded and commenced to amortize as of the date of the acquisition $11.3 million of other assets acquired from Abbott. Goodwill generated in connection with the acquisition of the Abbott business was reduced by these amounts (Note 4(a)). The impact of this revision of the purchase price allocation was to increase amortization expense by $0.9 million in 2003.

	2004	2003	2002(2)	2001	2000
		(restated)	(restated)		
		(in thousands, except per share data)			
Statement of Operations Data:					
Net product sales	$ 368,351	$ 286,984	$ 200,399	$ 47,268	$ 49,728
License revenue	8,559	9,728	6,405		
Net revenue	376,910	296,712	206,804	47,268	49,728
Cost of sales	227,548	168,171	114,653	26,662	26,796
Gross profit	149,362	128,541	92,151	20,606	22,932
Operating expenses:					
Purchased in-process research and development				6,980	
Research and development	31,954	24,280	14,471	1,810	1,360
Sales and marketing	57,957	52,504	39,544	8,018	7,540
General and administrative	52,707	35,452	28,066	11,702	7,048
Charge related to asset impairment			12,682		
Stock-based compensation		447	10,625	10,441	
Total operating expenses	142,618	112,683	105,388	38,951	15,948
Operating income (loss)	6,744	15,858	(13,237)	(18,345)	6,984
Interest expense and other expenses, net	(18,707)	(3,270)	(5,955)	(4,310)	(2,423)
(Loss) income from continuing operations before income taxes	(11,963)	12,588	(19,192)	(22,655)	4,561
Provision for income taxes	2,275	3,028	3,443	2,134	1,781
(Loss) income from continuing operations	$ (14,238)	$ 9,560	$ (22,635)	$ (24,789)	$ 2,780
(Loss) income from continuing operations available to common stockholders basic and diluted(1)	$ (14,987)	$ 8,602	$ (34,583)	$ (24,789)	$ 12,780
(Loss) income from continuing operations per common share(1):					
Basic (1)	$ (0.75)	$ 0.55	$ (3.48)	$ (3.89)	$ 0.59
Diluted (1)	$ (0.75)	$ 0.49	$ (3.48)	$ (3.89)	$ 0.59

	December 31,				
	2004	2003	2002	2001	2000

	December 31,				
		(restated)	(restated)		
			(in thousands)		
Balance Sheet Data:					
Cash and cash equivalents	$ 16,756	$ 24,622	$ 30,668	$ 52,024	$ 3,071
Working capital (deficit)	65,880	45,600	27,685	19,555	(6,464)
Total assets	567,178	539,999	356,495	278,521	74,958
Total debt	191,224	176,181	104,613	78,124	12,830
Redeemable convertible preferred stock		6,185	9,051	51,894	
Total stockholders' equity	274,681	266,080	161,849	89,614	41,812

(1) (Loss) income available to common stockholders and basic and diluted (loss) income per share are computed as described in notes 2(k) and 11 of our consolidated financial statements included elsewhere in this annual report on Form 10-K. Further, for the years ended December 31, 2001 and 2000, (loss) income available to common stockholders and basic and diluted

(loss) income per share are computed based upon the actual number of common shares issued and outstanding upon incorporation of our company in May 2001, adjusted for the fixed exchange ratio set forth in the merger agreement and related agreements and the related stock split as a result of the split-off and merger with Johnson & Johnson.

(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 principle which was subtracted from loss from continuing operations to arrive at net loss. Consequently, net loss available to common stockholders in 2002 was $46.7 million, or $4.70 per basic and diluted share.

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 (loss) income from continuing operations data of our company, as if no amortization of goodwill was recorded under SFAS No. 142 for all periods presented.

	Year Ended December 31,				
	2004	2003	2002	2001	2000
		(restated)	(restated)		
	(in thousands, except per share data)				
(Loss) income from continuing operations	$ (14,238)	$ 9,560	$ (22,635)	$ (24,789)	$ 2,780
Add back: Goodwill amortization, net of tax				398	398
Adjusted (loss) income from continuing operations	$ (14,238)	$ 9,560	$ (22,635)	$ (24,391)	$ 3,178
Adjusted (loss) income from continuing operations available to common stockholders basic and diluted	$ (14,987)	$ 8,602	$ (34,583)	$ (24,391)	$ 3,178
Adjusted (loss) income from continuing operations per common share(1):					
Basic	$ (0.75)	$ 0.55	$ (3.48)	$ (3.83)	$ 0.67
Diluted	$ (0.75)	$ 0.49	$ (3.48)	$ (3.83)	$ 0.67

(1)

(Loss) income available to common stockholders and basic and diluted (loss) income per share are computed as described in notes 2(k) and 11 of our consolidated financial statements included elsewhere in this annual report on Form 10-K. Further, for the years ended December 31, 2001 and 2000, (loss) income available to common stockholders and basic and diluted (loss) income per share are computed based upon the actual number of common shares issued and outstanding upon incorporation of our Company in May 2001, effected for the fixed exchange ratio set forth in the merger agreement and related agreements and the related stock split as a result of the split-off and merger with Johnson & Johnson.

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

Forward-Looking Statements

As noted above, this annual report on Form 10-K, including this Item 7, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Forward-looking statements in this Item 7 include, without limitation, statements regarding our expectations with respect to new product launches, research and development expenditures, legal expenditures, benefits to be realized as a result of synergies relating to our acquisitions, net product sales and gross profits from our various business segments, license revenue, our funding plans for our future working capital needs and commitments,

and the impact of our acquisitions. Actual results or developments could differ materially from those projected in such statements as a result of numerous factors, including, without limitation, those risks and uncertainties set forth below under "Certain Factors Affecting Future Results" and "Special Statement Regarding Forward-Looking Statements." The following discussion and analysis of our financial condition and results of operations should be read in light of those risks and uncertainties and in conjunction with our accompanying consolidated financial statements and notes thereto.

Financial Overview

Overall, 2004 was a challenging year for us. While we continued our sequential revenue growth revenues have grown from $47.3 million to $376.9 million in the three years since our split-off as an independent company we incurred a net loss of $14.2 million in 2004, compared to net income of $9.6 million in 2003. A reduction of approximately 175 basis points in our overall gross margin due to fluctuations in foreign currencies that are unfavorable to our core pregnancy product margins contributed to our loss in 2004. We will continue to be subject to the vagaries of foreign currency translation due to the extent of our reliance on foreign operations. Our overall gross margin was further reduced by approximately 187 basis points due to continued margin erosion in our nutritional supplements business, due primarily to aggressive price competition in this industry. Increased levels of research and development spending, primarily in the area of cardiology, and higher interest expense resulting primarily from our decision to refinance our debt in February 2004 also contributed to our loss.

Our continued revenue growth resulted from our acquisitions, primarily in our professional diagnostics business, and organic growth. Our acquisitions since the second half of 2003, including our acquisitions of the rapid diagnostics business from Abbott Laboratories in September and Applied Biotech, Inc., or ABI, in August, contributed approximately 60% of our currency adjusted revenue growth in 2004. Revenues also benefited from organic growth contributed by the launch of our Clearblue Easy Digital pregnancy test in June 2003, the commencement of our supply of the digital version of Pfizer's e.p.t pregnancy test in December 2003 and the visual version of Pfizer's e.p.t pregnancy test in June 2004, the launch of our Clearblue Easy Digital ovulation test in June 2004 and growth in our sales of rapid diagnostic tests for the point of care market.

As a leading global developer of advanced diagnostic devices, we are continually exploring opportunities in a variety of professional diagnostic and consumer-oriented applications, including immuno-diagnostics with a focus on women's health, cardiology and infectious disease. In 2004, we have executed several new point-of-care national distribution agreements and launched a new Clinical Laboratories Improvement Act of 1988 ("CLIA") waived strep throat test and tests for D-Dimer and Fecal Occult Blood.

On the other hand, our emphasis on new product development requires substantial investment and involves significant inherent risk. We intend to continue to devote substantial resources to research and development activities. Our recently announced co-development agreement with ITI Scotland Ltd., who will provide us with $57 million over three years to fund certain new and existing cardiovascular-related research and development initiatives, as well as development of our new cardiac center in Stirling, Scotland, is evidence of this commitment. In addition, we will continue to aggressively defend our substantial intellectual property portfolio, which underlies our emphasis on new product development, against potential infringers.

Our Acquisition of the Rapid Diagnostics Business from Abbott Laboratories

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

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

With respect to marketing synergies, we have enjoyed the savings that we anticipated at the time of the acquisition with respect to the addition of the Fact plus product line to our existing consumer diagnostics business, which has sold and distributed Fact plus with nominal increases in consumer sales and marketing infrastructure. These marketing synergies accounted for 34 basis points of the reductions in sales and marketing expense as a percentage of sales in 2004 reported below in the section entitled "Results of Operations Sales and Marketing Expense."

With respect to manufacturing synergies, during the second half of 2004, we transitioned the manufacturing of a portion of the Signify products from a third party manufacturer to our own manufacturing facilities. This transition was part of the original plan at the date of acquisition and resulted in increased gross profit of approximately $0.8 million on Signify product sales during the second half of 2004, as compared to the first half of 2004.

Other manufacturing synergies anticipated at the time of the acquisition include the transition of the TestPack products to our product design and manufacturing capacity. This product transition is currently anticipated late in the first quarter of 2005 for all countries except Japan, where the transition will occur in the fourth quarter of 2005. We currently anticipate achieving synergies in line with our expectations as of the date of acquisition. Additional manufacturing synergies were anticipated as we transition production of Fact plus for the international market to our own manufacturing operations. We began this transition by taking over production of Fact plus made for sale to one very small target market in the second quarter of 2004 and we transitioned the vast majority of production of the pregnancy tests acquired from Abbott for the international markets in the fourth quarter of 2004 which, along with improved pricing due to distribution changes, resulted in a 12% increase in gross profit earned from Fact plus and international pregnancy sales in the fourth quarter of 2004 as compared to the third quarter of 2004. Benefits that may arise from synergies between combined businesses, including the benefits arising out of synergies relating to our acquisition of the rapid diagnostics

business from Abbott, are subject to the risks relating to our acquisitions, as well as the other numerous risks that our business faces set forth in the sections of this report entitled "Certain Factors Affecting Future Results" and "Special Statement Regarding Forward-Looking Statements."

Results of Operations

Year Ended December 31, 2004 Compared to Year Ended December 31, 2003

Net Product Sales. Net product sales increased by $81.4 million, or 28%, to $368.4 million in 2004 from $287.0 million in 2003. Excluding the favorable impact of currency translation, net product sales in 2004 grew by approximately $71.0 million, or 25%, over 2003. A significant portion of the revenue increase resulted from our acquisitions in 2003 and 2004: (i) ABI contributed $14.0 million of such increase, (ii) the rapid diagnostics business of Abbott contributed $28.1 million, and (iii) various less significant acquisitions contributed an aggregate of $5.6 million of such increase. The remaining currency adjusted net product sales increase of $23.3 million resulted from our organic growth, primarily due to the launch of our Clearblue Easy Digital pregnancy test in June 2003, the commencement of our supply of the digital version of Pfizer's e.p.t pregnancy test in December 2003 and the visual version of Pfizer's e.p.t pregnancy test in June 2004, the launch of our Clearblue Easy Digital ovulation test in June 2004 and growth in our sales of rapid diagnostic tests for the point-of-care market.

Net Product Sales by Business Segment. Net product sales by business segment for 2004 and 2003 are as follows:

(in thousands)	2004	2003 (restated)	% Increase
Consumer diagnostic products	$ 158,706	$ 127,056	25%
Vitamins and nutritional supplements	77,923	71,637	9%
Professional diagnostic products	131,722	88,291	49%
Total net product sales	$ 368,351	$ 286,984	28%

The currency adjusted increase in net product sales from our consumer diagnostic products was $23.6 million, or 19%, comparing 2004 to 2003. Of the currency adjusted increase, $1.2 million and $7.6 million resulted from the acquisition of ABI and Abbott's Fact plus line of consumer diagnostic pregnancy tests, respectively. The remaining currency adjusted increase of $14.8 million resulted from our organic growth, primarily due to the launch of our Clearblue Easy Digital pregnancy test in June 2003, the commencement of our supply of the digital version of Pfizer's e.p.t pregnancy test in December 2003 and the visual version of Pfizer's e.p.t pregnancy test in June 2004, and the launch of our Clearblue Easy Digital ovulation test in June 2004.

Net product sales of our vitamins and nutritional supplements increased by $6.3 million, or 9%, comparing 2004 to 2003. The increase was primarily in our private label nutritional supplements sales.

The currency adjusted increase in net product sales from our professional diagnostic products was $41.0 million, or 46%, comparing 2004 to 2003. Of the currency adjusted increase, $12.8 million resulted from the acquisition of ABI, $20.5 million resulted from the acquisition of the Abbott Testpack and Signify product lines and an aggregate of $5.6 million resulted from various less significant acquisitions. The remaining currency adjusted increase of $2.1 million resulted from our organic growth, primarily due to increased sales of our rapid diagnostic tests for the point of care market. We expect our professional diagnostics business to continue to grow as we signed several new point-of-care national distribution agreements in the second half of 2004 and as we have recently introduced new products, such as a CLIA waived strep throat test and tests for D-Dimer and Fecal Occult Blood.

Net Product Sales by Geographic Location. Net product sales by geographic location for 2004 and 2003 are as follows:

(in thousands)	2004	2003 (restated)	% Increase
United States	$ 221,170	$ 182,580	21%
Europe	98,136	69,594	41%
Other	49,045	34,810	41%
Total net product sales	$ 368,351	$ 286,984	28%

The growth in our US business resulted primarily from the full year effect of the 2003 acquisitions of ABI and the portion of the Abbott rapid diagnostic business distributed in the US, as well as the launch of our Clearblue Easy Digital pregnancy test in June 2003, the commencement of our supply of the digital version of Pfizer's e.p.t pregnancy test in December 2003 and the visual version of Pfizer's e.p.t pregnancy test in June 2004, and the launch of our Clearblue Easy Digital ovulation test in June 2004. Our growth in Europe and the rest of the world was primarily attributable to the portion of the Abbott rapid diagnostic business distributed in each geography, as well as, with respect to Europe, the sales contributions from various less significant acquisitions.

License Revenue. License revenue represents license and royalty fees from intellectual property license agreements with third-parties. License revenue decreased by $1.1 million, or 11%, to $8.6 million in 2004 from $9.7 million in 2003. The decrease is a function of the net results of royalties collected under new licenses and a decrease in royalties under expired licenses. We expect license revenue to continue to decrease in 2005 as we ceased collection of royalty fees from Pfizer in the fourth quarter of 2004, which we have been collecting since June 2003 as part of the settlement of our infringement actions against it.

Gross Profit and Margin. Gross profit increased by $20.9 million, or 16%, to $149.4 million in 2004 from $128.5 million in 2003. Included in cost of sales in 2004 was a $1.7 million restructuring charge covering all costs for severance, early retirement and outplacement services arising from a completed plan of termination at our manufacturing facility in Bedford, England. The total number of involuntarily terminated employees was 18, all of whom were terminated as of December 31, 2004. As of December 31, 2004, substantially all restructuring costs were paid. Excluding this charge, gross profit increased by $22.6 million, or 18%, comparing 2004 to 2003.

The gross profit increase of $22.6 million, comparing 2004 to 2003 and adjusted for the restructuring charge, as discussed above, primarily resulted from the businesses that we acquired in the second half of 2003. The acquisition of ABI contributed $4.3 million of such gross profit increase. The rapid diagnostics business we acquired from Abbott contributed $15.6 million of such gross profit increase and its gross margin increased to 51% in 2004 from 39% in 2003 as a result of our transitioning the manufacturing of a portion of the Signify and Fact plus products from a third-party manufacturer to our own manufacturing facility. The increased profitability arising from our transition of production of Signify to our own manufacturing is attributable to synergies that we expected to benefit from when we acquired the Abbott rapid diagnostics business and we expect to recognize additional benefits as we continue to transition production of TestPack to our own facilities. The remaining increase of $2.7 million in our gross profit, adjusted for the restructuring charge, as discussed above, was primarily a result of the launch of our Clearblue Easy Digital pregnancy and ovulation tests, the commencement of our supply of the Pfizer e.p.t products and the growth in our professional diagnostics base business, while offset by declining profits from our nutritional supplements business. Gross profit from our nutritional supplements business, principally the private label products, declined by $5.8 million, comparing 2004 to 2003, while its sales increased by $6.3 million. Our private label

nutritional supplements business has suffered from excess capacity in the industry which has led to increased price competition.

Overall gross margin was 40% in 2004, compared to 43% in 2003. The restructuring charge, as discussed above, had the effect of reducing gross margin by 46 basis points in 2004. Gross margin was also adversely impacted in 2004 by the continuing weak U.S. Dollar against the Euro and British Pounds Sterling. Such movements in foreign exchange currencies negatively impacted the gross margin percentage of our products manufactured at our European subsidiaries and sold in U.S. Dollars. This currency impact had the effect of reducing gross margins by 175 basis points, comparing 2004 to 2003. Further, as discussed above, due to competitive pricing in the nutritional supplements business, gross margin from our nutritional supplements sales, principally in our private label products, has declined significantly. Comparing 2004 to 2003, the margin erosion of the nutritional supplements business affected our overall gross margin by 187 basis points. Somewhat offsetting the negative impact on gross margin was the improved gross margin of the rapid diagnostic products of Abbott, as discussed above.

Gross Profit from Net Product Sales by Business Segment. Gross profit from net product sales represents total gross profits less gross profit associated with license revenue. Gross profit from total net product sales increased by $22.0 million, or 18%, to $144.1 million in 2004 from $122.1 million in 2003. Gross profit from net product sales by business segment for 2004 and 2003 are as follows:

(in thousands)	2004	2003 (restated)	% Increase
Consumer diagnostic products	$ 82,909	$ 70,910	17%
Vitamins and nutritional supplements	8,775	14,577	(40)%
Professional diagnostic products	52,437	36,586	43%
Total gross profit from net product sales	$ 144,121	$ 122,073	18%

Gross profit from our consumer diagnostic product sales increased by $12.0 million, or 17%, comparing 2004 to 2003. Of the increase in gross profit from our consumer diagnostic product sales, $4.0 million resulted from our acquisition of the Fact plus line of consumer diagnostic pregnancy tests from Abbott in September 2003. Organic growth, primarily as a result of the launch of our Clearblue Easy Digital pregnancy and ovulation tests and the commencement of our supply of the e.p.t pregnancy tests to Pfizer, contributed to the remaining increase in our gross profit from our consumer diagnostic product sales.

Gross margin from our consumer diagnostic product sales was 52% in 2004, compared to 56% in 2003. The restructuring charge, as discussed above, had the effect of reducing gross margin from our consumer diagnostic product sales by 109 basis points, comparing 2004 to 2003. The movements in foreign currencies, comparing 2004 to 2003, negatively impacted gross margin by 416 basis points for our consumer diagnostic products manufactured at our European subsidiaries and sold in U.S. Dollars. The negative margin impact of the restructuring charge and foreign currency movements was offset in part by the sales of our digital pregnancy tests, which, as state-of-the-art, first-to-market products are able to generate higher gross profit per unit sold than traditional pregnancy tests.

Despite sales increase, as discussed above, gross profit from our nutritional supplements business, principally the private label products, declined by $5.8 million, or 40%, comparing 2004 to 2003, as a result of margin erosion due to pricing competition. This was evident by its gross margin of 11% in 2004, compared to 20% in 2003.

The increase in gross profit from our professional diagnostic product sales of $15.9 million, comparing 2004 to 2003, primarily resulted from our acquisitions of the Abbott TestPack and Signify product lines and ABI. The Abbott professional diagnostic products contributed $11.7 million of the

increase in gross profit, comparing 2004 to 2003. The acquisition of ABI contributed $4.3 million of the increase in gross profit from our professional diagnostic product sales.

Gross margin from our professional diagnostic product sales was 40% in 2004, compared to 41% in 2003. The decline in gross margin of our professional diagnostic products primarily resulted from the ABI products which on average have been generating lower margins than our other professional diagnostic products.

Research and Development Expense. Research and development expense increased by $7.7 million, or 32%, to $32.0 million in 2004 from $24.3 million in 2003. A significant portion of our research and development spending occurs at our facilities in the United Kingdom. As a result, the weak U.S. Dollar against the British Pounds Sterling causes an increase in the dollar value of research and development expense at translation. Adjusted for the unfavorable impact of currency translation, research and development expense increased by $5.2 million, or 21%, when comparing 2004 to 2003. Our acquisition of ABI, primarily in the field of professional diagnostic testing, contributed $1.6 million of the currency adjusted increase in research and development expense. The remaining increase in research and development expense, comparing 2004 to 2003, resulted from an increase in our cardiology research and development expenditures from $11.3 million in 2003 to $17.9 million in 2004 (an increase of $4.7 million on a currency adjusted basis).

We recently executed a co-development agreement with ITI Scotland Limited, which will provide us with $57.0 million over three years to fund certain new and existing cardiovascular-related research and development initiatives, as well as development of our new cardiac center in Stirling, Scotland. While we expect to expand our research and development efforts, we also expect our research and development spending to decrease in 2005 due to the co-development funding arrangement in Scotland.

Sales and Marketing Expense. Sales and marketing expense increased by $5.5 million, or 10%, to $58.0 million in 2004 from $52.5 million in 2003. A significant portion of our sales and marketing spending takes place at our European subsidiaries. Accordingly, and as a result of the continued weak U.S. Dollar, the currency adjusted increase in sales and marketing expense, comparing 2004 to 2003, was $3.1 million, or 6%. Of the currency adjusted increase in sales and marketing expense, $2.4 million resulted from the amortization of customer related intangible assets which we acquired as part of our acquisition of the rapid diagnostics business of Abbott. The remaining currency adjusted increase in sales and marketing expense of $0.7 million resulted from our acquisition of ABI.

Sales and marketing expense as a percentage of net product sales decreased to 16% in 2004, from 18% in 2003. The percentage decrease primarily resulted from the shift to our professional diagnostics business which generally incurs lower sales and marketing expense as a percentage of sales from our vitamins and nutritional supplements business. In addition, marketing synergies realized due to our integration of the Fact plus product line acquired from Abbott with only nominal increases in consumer sales and marketing infrastructure accounted for approximately 34 basis points of the reduction in sales and marketing expense as a percentage of sales from 2003 to 2004.

General and Administrative Expense. General and administrative expense increased by $17.2 million, or 48%, to $52.7 million in 2004 from $35.5 million in 2003. Excluding the impact of foreign currency translation, general and administrative expense increased $15.6 million, or 44%, when comparing 2004 to 2003. Included in general and administrative expense for 2004 was the establishment of a specific reserve for a doubtful accounts receivable balance of $1.4 million. Legal expenses in 2004 increased by $4.0 million, compared to 2003, due to our active pursuits and defenses in litigations, primarily related to intellectual property infringements. Our acquisitions since June 2003 contributed an additional $6.6 million to general and administrative expenses in 2004, compared to 2003. In 2004, we also spent an additional $1.7 million in audit and consulting costs associated with our preparation for compliance under the Sarbanes-Oxley Rule 404 regarding internal control over financial reporting. The

remaining currency adjusted increase of $1.9 million in general and administrative expense from 2003 to 2004 resulted from investments in our infrastructure to support the growth of our business. For the factors discussed herein, general and administrative expense as a percentage of net revenue increased to 14% in 2004 from 12% in 2003.

Interest Expense. Interest expense includes interest charges, the write-off and amortization of deferred financing costs and the amortization of 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 increased by $12.4 million, or 128%, to $22.1 million in 2004 from $9.7 million in 2003. In 2004, we recorded a charge of $3.8 million representing the write-off of deferred financing costs and prepayment fees and penalties related to the repayment of borrowings under our primary senior credit facility and certain subordinated notes with the proceeds from our $150.0 million bond offering in February 2004. Excluding such charge, interest expense increased by $8.6 million, comparing 2004 to 2003. Such increase was primarily due to a higher average outstanding debt balance which was $183.7 million during 2004, compared to $140.4 million during 2003, primarily as a result of the borrowings to finance the acquisitions of ABI and the rapid diagnostics business from Abbott in the second half of 2003. Additionally, the 8.75% interest rate on the $150.0 million bonds increased our average cash interest rate to 8.7% as of December 31, 2004, compared to 6.1% as of December 31, 2003. The bonds, which are due in 2012, provide us with a long-term fixed rate on a significant portion of our indebtedness, as compared to the variable rates under our senior credit facilities.

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)	2004	2003
Interest income	$ 1,050	$ 1,043
Foreign exchange (losses) gains, net	(720)	5
Other	3,077	5,393
Total other income (expense), net	$ 3,407	$ 6,441

The foreign exchange loss of $0.7 million in 2004 primarily resulted from the continuing weakening U.S. Dollar against the British Pounds Sterling and the Euro, as certain receivables of our Irish and U.K. subsidiaries are denominated in U.S. Dollar while their functional currency is their respective local currency.

Included in other income for 2004 are the following items: (i) $0.5 million of royalties received attributable to periods prior to 2004 associated with a license arrangement that had historically been underpaid, (ii) $0.9 million in release of a pre-acquisition legal contingency reserve upon reaching and signing a settlement agreement, and (iii) $0.5 million in litigation settlement gain. Included in other income for 2003 is $1.2 million of past royalties received as part of a patent infringement settlement and a one-time gain of $3.8 million recorded in connection with an agreement with Unilever Plc (the seller of the Unipath business) which resolved certain issues that arose out of our acquisition of the Unipath business.

Provision for Income Taxes. Provision for income taxes decreased by $0.7 million, or 23%, to $2.3 million in 2004 from $3.0 million in 2003. The effective tax rate in 2004 was (19)%, compared to 24% in 2003. The decrease in the provision for income taxes from 2003 to 2004 related to the recognition and benefit of certain current year losses and certain deferred tax assets. In 2004, we recognized $0.8 million of benefit from the reduction of the valuation allowance related to net operating loss, or NOL, carryforward of two of our foreign subsidiaries due to our assessment that we would more likely than not realize the benefit of these NOLs. The primary component of the 2004 provision for income taxes related to the recognition of a U.S. deferred tax liability for temporary differences between the book and tax bases of goodwill and certain intangible assets with indefinite lives.

Net (Loss) Income. We incurred a net loss of $14.2 million in 2004, while we generated net income of $9.6 million in 2003. After taking into account charges for redemption interest and amortization of a beneficial conversion feature related to our Series A redeemable convertible preferred stock, we had a net loss available to common stockholders of $15.0 million, or $0.75 per basic and diluted common share, in 2004, compared to net income available to common stockholders of $8.6 million, or $0.55 and $0.49 per basic and diluted common share, respectively, in 2003. The net loss in 2004 and net income in 2003 primarily resulted from the various factors as discussed above. See note 11 of our consolidated financial statements included elsewhere in this annual report on Form 10-K for the calculation of net (loss) income per share.

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 business 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 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 diagnostic products	$ 127,056	$ 109,450	16%
Vitamins and nutritional supplements	71,637	57,909	24%
Professional diagnostic products	88,291	33,040	167%
Total net product sales	$ 286,984	$ 200,399	43%

The increase of $17.6 million, or 16%, in net product sales from our consumer diagnostic products from 2002 to 2003 primarily resulted from our organic growth, including the launch of our Clearblue Easy Digital pregnancy test in June 2003. Our acquisition of Abbott's Fact plus line of consumer diagnostic pregnancy tests contributed $2.3 million of the increase in net product sales from our consumer diagnostic products.

Net product sales of our vitamins and nutritional supplements increased by $13.7 million, or 24%, from 2002 to 2003, which primarily resulted from our acquisition of the IMN business.

The increase of $55.3 million in net product sales from our professional diagnostic products from 2002 to 2003 primarily resulted from our acquisitions of Ostex, Wampole, ABI and the Abbott TestPack, Abbott TestPack and Signify product lines from Abbott. The addition of the Wampole business in September 2002, the Ostex business in June 2003 and the ABI business in August 2003 contributed $2.0 million, $33.3 million and $7.4 million, respectively, of the increase in net product sales from our professional diagnostic products. The products from the Abbott business contributed $8.9 million of the increase. The remaining increase in net product sales from our professional diagnostic products resulted from organic growth.

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 of $75.8 million 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, as discussed above in the comparison of net product sales by business segments. Our acquisition of the Signify product line from Abbott, which is primarily sold in the United States, contributed $4.7 million to the increase in net product sales in the United States. The remaining increase in net product sales in the United States resulted from the organic growth of our business, including the launch of our Clearblue Easy Digital pregnancy test. 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 and Fact plus product lines, Ostex and ABI, which in the aggregate contributed $4.6 million of the $9.1 million increase. In addition, IMN and Wampole recorded higher sales in Canada by $1.6 million 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 $0.6 million in license revenue in 2003 compared to $0.2 million in 2002. The remainder of the increase in license revenue resulted from increased sales and minimum royalty payments by certain of our licensees.

Gross Profit and Margin. Gross profit increased by $36.3 million, or 39%, to $128.5 million in 2003 from $92.2 million in 2002. The increase in gross profit 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 business from Abbott contributed $4.3 million of such increase. The increase of $3.3 million in license revenue from 2002 to 2003, as discussed above, also contributed

to the increase in gross profit. The remaining increase in gross profit from 2002 to 2003, or $14.4 million, primarily resulted from organic growth, including the launch of our 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 was 43% in 2003 compared to 45% 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 170 basis points from 2002 to 2003. In addition, the decline in overall gross margin 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 110 basis points reduction in the overall gross margin. Partially offsetting the negative impact to gross margin due to foreign currency movements and the Wampole and Abbott products were increased license revenue and sales of our Clearblue Easy Digital pregnancy test in 2003, the latter of which, as a state-of-the-art, first-to-market product, generates higher gross profit per unit sold than most of our other consumer diagnostic products.

Gross Profit from Net Product Sales by Business Segment. Gross profit from net product sales represents total gross profits less gross profit associated with license revenue. Gross profit from total net product sales increased by $33.5 million, or 38%, to $122.1 million in 2003 from $88.6 million in 2002. Gross profit from net product sales by business segment for 2003 and 2002 are as follows:

	2003	2002	% Increase
(in thousands)		**(restated)**	
Consumer diagnostic products	$ 70,910	$ 60,731	17%
Vitamins and nutritional supplements	14,577	12,230	19%
Professional diagnostic products	36,586	15,688	133%
Total gross profit from net product sales	$ 122,073	$ 88,649	38%

The increase in gross profit from our consumer diagnostic 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. Gross margin from our consumer diagnostic product sales was 56% and 55% in 2003 and 2002, respectively. Movements in foreign currencies negatively impacted the gross margin from our consumer diagnostic product sales by 373 basis 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 diagnostic products was offset by the organic growth in our women's health care sales, including the sales of our Clearblue Easy Digital pregnancy test, which as a state-of-the-art, first-to-market product generates higher gross profit per unit sold than most of our other consumer diagnostic products.

Approximately $0.6 million of the increase in gross profit from our vitamins and nutritional supplements product sales from 2002 to 2003 resulted from our acquisition of IMN. The remaining increase of $1.7 million primarily resulted from the transition of the manufacturing of our branded products from third party suppliers to our own facility at IMN. Gross margin of our vitamins and nutritional supplement product sales was 20% in 2003, compared to 21% in 2002.

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 products acquired from Abbott that was being manufactured or sold by Abbott under transition agreements also generated 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. To a lesser extent, our acquisitions of Ostex and ABI contributed to the increase in research and development expense from 2002 to 2003.

Sales and Marketing Expense. Sales and marketing expense increased by $13.0 million, or 33%, to $52.5 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, ABI and the Abbott business contributed $1.7 million of the increase in sales and marketing expense, of which $0.8 million represented amortization of the customer related intangible assets acquired as part of the Abbott business. 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.

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 $0.6 million representing a reimbursement by insurance of legal costs previously incurred in connection with a lawsuit, for which we assumed the defense when we acquired the Unipath business in December 2001. In addition, another $0.2 million 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.

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 business acquired from Abbott, for which we have not incurred significant incremental general and administrative costs in 2003.

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 2003.

Stock-Based Compensation Expense. Stock-based compensation expense was $0.4 million 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. The majority of the 2002 expense related 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 $0.5 million 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.

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 $0.5 million 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 business from Abbott, but partially offset by lower average interest rates in 2003.

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**
Interest income	$ 1,043	$ 1,423
Foreign exchange gains (losses), net	5	(1,618)
Other	5,393	9,309
Total other income (expense), net	$ 6,441	$ 9,114

Interest income decreased by $0.4 million, 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 $0.2 million 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 $20.0 million in subordinated promissory notes in March 2002.

Provision for Income Tax. Provision for income taxes decreased by $0.4 million, or 10%, to $3.0 million in 2003 from $3.4 million in 2002. The effective tax rate was 24% in 2003 compared to 18% in 2002. The increase in the effective tax rate from 2002 to 2003 related to the recognition of certain deferred tax liabilities. The deferred tax liabilities relate to the U.S. goodwill and other indefinite-lived intangible assets acquired in the purchases of Wampole and the rapid diagnostics business from Abbott. Of the 2003 provision for income taxes, $1.8 million related to the U.S. goodwill and other indefinite-lived intangible assets and $0.9 million related to the Unipath business. The remaining businesses recorded state or local tax provisions totaling $0.3 million.

Income (Loss) before Cumulative Effect of a Change in Accounting Principle. We generated income before cumulative effect of a change in accounting principle in 2003 of $9.6 million while in 2002 we incurred a loss before cumulative effect of a change in accounting principle of $22.6 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 before cumulative effect of a change in accounting principle available to common stockholders of $8.6 million, or $0.55 and $0.49 per basic and diluted common share, respectively, in 2003 and a loss before cumulative effect of a change in accounting principle available to common stockholders of $34.6 million, or $3.48 per basic and diluted common share, in 2002. The addition of Wampole in September 2002 and the rapid diagnostics business from Abbott in September 2003 contributed an incremental income of $2.0 million and $2.9 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. See note 11 of our consolidated financial statements included elsewhere in this annual report on Form 10-K for the calculation of income (loss) per share before cumulative effect of a change in accounting principle.

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 a valuation of 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 during 2003.

Net Income (Loss). We generated net income in 2003 of $9.6 million while in 2002 we incurred a net loss of $34.8 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 $8.6 million, or $0.55 and $0.49 per basic and diluted common share, respectively, in 2003 and a net loss available to common stockholders of $46.7 million, or $4.70 per basic and diluted common share, in 2002. The addition of Wampole in September 2002 and the rapid diagnostics business from Abbott in September 2003 contributed incremental income of $2.0 million and $2.9 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. See note 11 of our consolidated financial statements included elsewhere in this annual report on Form 10-K for the calculation of net income (loss) per share.

Liquidity and Capital Resources

Based upon our current working capital position, current operating plans and expected business conditions, we believe that our existing capital resources, credit facilities and expected funding resulting from our recently executed co-development funding agreement with ITI Scotland Limited will be adequate to fund our operations, including our outstanding debt and other commitments, as discussed below, for the next 12 months. In the long-run, we expect to fund our working capital needs and other commitments primarily through the co-development funding program with ITI Scotland Limited and through our operating cash flow, since we expect to grow our business through new product introductions and by continuing to leverage our strong intellectual property position. Our recent cost savings initiatives, including the move of certain of our manufacturing to China and the consolidation of our U.S. packaging and distribution facilities, should help fund our working capital needs and commitments as well, both in the short- and long-term. We also expect to rely on our credit facilities to fund a portion of our capital needs and other commitments.

Additionally, on February 2, 2005, our IMN subsidiary received $8.4 million representing its pro rata share of the net funds which were dispersed in connection with the settlement of class action suits against several raw material suppliers. The class action suits alleged that certain defendants unlawfully agreed to fix prices of certain ingredients used to produce vitamin and nutritional supplement products sold in the United States. IMN's recovery represented 7.3% of its approved purchases from the settling parties during the period in which the price fixing was alleged.

Our funding plans for our working capital needs and other commitments may be adversely impacted by unexpected costs associated with prosecuting and defending our existing lawsuits and/or unforeseen lawsuits against us, integrating the rapid diagnostics business acquired from Abbott Laboratories and executing our cost savings strategies. 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 own. 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, 2004, we had cash and cash equivalents of $16.8 million, a $7.9 million decrease, or 32%, from December 31, 2003. Since our split-off from our former parent company in November 2001, we have funded our business through operating cash flows, proceeds from borrowings and the issuance of equity securities. During 2004, we generated cash of $8.3 million from our operating activities, which resulted from income, adjusted for non-cash items, of $15.2 million, offset by a net working capital increase, excluding the change in cash balance, of $6.9 million. The increase in working capital primarily resulted from a significant increase in inventories and an increase in our accounts receivable balance. Inventory increased due to the transition of the manufacturing of the Signify product line we acquired from Abbott in September 2003 from a third party manufacturer to our own facilities and a build-up of inventory in the professional diagnostics business to support our distribution agreements entered into in 2004. Our accounts receivable balance increased due to increase in sales. Our non-equity financing activities, primarily the issuance of $150 million in bonds in February 2004, net of repayments of borrowings under our primary senior credit facility and certain subordinated notes and bond origination costs, provided us with cash of $15.2 million during 2004. In addition, we received $1.9 million in proceeds from the exercises of common stock options during 2004.

In 2004, we used cash of $34.3 million for investing activities which consisted of $12.4 million paid for transaction costs associated with previously acquired businesses and the acquisitions of Viva Diagnostika, or Viva, and Advantage Diagnostics Corporation, or ADC, in 2004 and for the acquisition of certain intellectual property, $20.0 million in capital expenditures, net of proceeds from sales of equipment and an increase in other non-current assets of $1.9 million. Fluctuations in foreign currencies positively impacted our cash balance by $1.0 million in 2004.

Investing Activities

During 2004, we incurred $20.0 million in capital expenditures, net of proceeds from sales of equipment. We incurred capital expenditures of approximately $4.5 million in connection with the cardiology products, $2.1million in machinery in connection with the transition of the manufacturing of the Abbott rapid diagnostic products from Abbott and $1.2 million for new tools and capacity expansion related to the manufacture of a new format of our drugs of abuse test and plant capacity expansions at our ABI subsidiary. We also continued to make significant investment in laboratory instrument systems that we placed with our customers in connection with our roll out of certain of our professional diagnostic products, which amounted to $1.8 million in 2004. Other miscellaneous capital expenditures during 2004 included: (i) approximately $0.9 million for the preparation of our facilities for the manufacture of the visual version of Pfizer's e.p.t pregnancy test which we began to sell to Pfizer in June 2004, (ii) $0.9 million in computer software in connection with the implementation of the SAP system in our U.S. facilities, (iii) $1.8 million primarily in leasehold improvements in connection with our initiative to consolidate our U.S. distribution facility, and (iv) $1.1 million in connection with our initiative to move certain of our manufacturing to China. The remaining capital expenditures in 2004 were incurred for the purchase of additional equipment to support our organic growth and various research and development activities.

On June 16, 2004, we acquired ADC, a closely held lateral flow diagnostic company that specializes in rapid test development and component manufacturing. The purchase price of ADC consisted of $2.4 million in cash and $0.2 million in assumed debt. The terms of the merger agreement also provide for $1.5 million of contingent consideration payable to the ADC shareholders upon the successful completion of a new product under development by December 31, 2005. We believe that the acquisition of ADC and the addition of ADC's chief scientist to our existing staff will deepen our scientific research management and expand our intellectual property capabilities.

On June 2, 2004, we acquired Viva, a closely held distributor of professional diagnostic products to the German marketplace. The purchase price for Viva consisted of $2.6 million in cash, 155,000 shares of our common stock with an aggregate fair value of $3.0 million and approximately $0.3 million in assumed debt. We believe that Viva, with its established German distribution network, will provide us with expanded distribution channel for our professional diagnostic products, as well as for our cardiac products in development.

On January 24, 2005, we completed the acquisition of the consumer pregnancy test business of Advanced Clinical Systems Pty Ltd for $4.6 million. In acquiring the business, we obtained the rights to the Crystal Clear brand. Crystal Clear is the leading consumer pregnancy test in Australia and has a leading position in New Zealand.

On February 8, 2005, we entered into a definitive merger agreement with Binax, Inc., or Binax, whereby we would acquire 100% of Binax's outstanding common stock. Binax is engaged primarily in the business of developing, manufacturing, marketing and selling rapid diagnostic tests for the detection of infectious diseases, which tests enable pathogen-specific identification that aid doctors in treatment decisions at the point-of-care. The addition of Binax is expected to be a continuation of our strategic efforts focused on expanding our proprietary technology base and product offerings. We expect to benefit from Binax's established reputation in respiratory diagnostics and the potential new product development opportunities. The merger consideration will consist of (i) 1,433,333 shares of our common stock, (ii) $8.6 million in cash less the amount by which expenses incurred by Binax in connection with the merger transaction exceed $0.2 million, and (iii) contingent cash consideration of up to $11.0 million to become payable, if at all, upon the commercialization during the five years following the merger of certain products. We expect to fund the cash portion of the merger consideration to acquire Binax using our senior credit facility.

On February 16, 2005, we entered into a definitive agreement to acquire Ischemia Technologies, Inc., or Ischemia, for approximately $22.4 million of our common stock subject to adjustment for certain allocated expenses and liabilities. We plan to finance payment of approximately $3.5 million in assumed, acquisition-related liabilities using our senior credit facility. Using patented intellectual property rights, Ischemia has developed and manufactures and markets the only FDA-cleared in vitro diagnostic test specifically targeted on cardiac ischemia, known as Ischemia Modified Albumin, or IMA. With IMA, when used in conjunction with established ECG and troponin tests, emergency physicians can quickly rule out from three to five times more patients whose chest pain symptoms derive from non-cardiac conditions. We expect the acquisition of Ischemia to be a natural fit with our declared strategy of bringing to market unique cardiac markers and delivery platforms that have the capability to substantially change the diagnosis of cardiovascular disease.

Financing Activities

On February 10, 2004, we completed the sale of $150.0 million of 8.75% 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 proceeds was used for Bond offering expenses and general corporate purposes.

These 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. In addition, under the related registration rights agreement, we were to cause the registration statement with the Securities and Exchange Commission, or SEC, with respect to a registered exchange offer to exchange the notes underlying the bonds for new

notes, to be declared effective under the Securities Act of 1933, as amended, within 240 days after the date of the bonds issuance and consummate the exchange offer within 270 days after the date of the bonds issuance. As we were unable to register the exchange offer within the number of days specified, interest on the bonds increased by 0.25% point per year for the first 90-day period immediately following the default and an additional 0.25% point per year with respect to each subsequent 90-day period up to a maximum amount of additional interest of 1% point. Consequently, as of December 31, 2004, the interest rate at which we accrue interest on the bonds was 9%. For the period January 7, 2005 through the date hereof, we are accruing interest at 9.5%. On February 14, 2005, we caused the registration statement with respect to the exchange offer to be declared effective and we expect to consummate the registered exchange offer by mid March 2005. As of December 31, 2004, total accrued interest related to the bonds amounted to $5.0 million.

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. 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.

Our primary senior credit facility with a group of banks, as amended, currently provides us with revolving lines of credit in the aggregate amount of up to $50.0 million, subject to continuing covenant compliance. Prior to the repayment of all borrowings under this senior credit facility using the proceeds from our bond offering in February 2004, as discussed above, we had obtained term loans aggregating $84.9 million and had drawn upon the revolving lines of credit in the aggregate amount of $39.9 million. Since the repayment of the borrowings under the senior credit facility in February 2004 through December 2004, we had drawn approximately $4.9 million, net of repayments, from the revolving lines of credit to fund our working capital requirements. Further, in October 2004, we borrowed an additional $15.2 million under this senior credit facility to refinance the then outstanding borrowings under IMN's senior credit facility and bonds payable. Consequently, at December 31, 2004, we had $20.1 million of outstanding borrowings under the revolving lines of credit. In January 2005, we borrowed an additional $11.0 million under the revolving lines of credit, primarily to finance the

interest payment of the bonds that was due in February 2005 and the acquisition of the consumer pregnancy test business of Advanced Clinical Systems Pty Ltd in January 2005.

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 2.75% to 3.75% or 1.50% to 2.50%, respectively, depending on the quarterly adjustments that are based on our consolidated financial performance. As of December 31, 2004, the applicable interest rate under the revolving lines of credit, including the applicable margin, was 6.15%.

Borrowings under our primary senior credit facility 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 Orgenics Ltd., our Israeli subsidiary, Inverness Medical Shanghai Co., Ltd., our subsidiary in China, Inverness Medical Australia Pty. Ltd., our Australian subsidiary, and Unipath Scandinavia AB, our Swedish subsidiary, and the stock of Orgenics and certain smaller subsidiaries. Under the senior credit agreement, as amended, 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, depreciation and amortization, or EBITDA, and a minimum cash requirement. Additionally, the senior credit agreement currently prohibits us from paying dividends. We are currently 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 and the consent of our senior lenders. Prepayments are made 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. An entity controlled by our chief executive

officer purchased 3% convertible notes in the aggregate principal amount of $3.0 million. The 9% subordinated notes and 3% convertible notes accrued interest on the outstanding principal amount at 9% and 3% per annum, respectively, which was payable quarterly in arrears on the first day of each calendar quarter starting October 1, 2002.

In February 2004, we prepaid the outstanding balance of the 9% subordinated notes, or $9.0 million, and a consequential prepayment penalty of $180,000 with the proceeds from the Bond issuance, as discussed above.

The 3% subordinated notes were set to mature on September 20, 2008, subject to acceleration in certain circumstances. In addition, the outstanding principal amount and unpaid interest on the 3% convertible notes would 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 was greater than $22.67, which event occurred on December 8, 2004. Consequently, on December 8, 2004, the 3% subordinated notes and accrued and unpaid interest converted into 345,784 shares of our common stock.

As of December 31, 2004, we had an aggregate of $2.2 million in outstanding capital lease obligations which are payable through 2009.

In January 2004, all of our then outstanding Series A redeemable convertible preferred stock, or 208,060 shares, were converted at our option into 416,120 shares of our common stock.

Income Taxes

As of December 31, 2004, we had approximately $105.3 million and $25.9 million of domestic and foreign net operating loss, or NOL, carryforwards, respectively, which either expire on various dates through 2024 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. In addition, the domestic operating loss carryforward amount at December 31, 2004 included approximately $48.5 million of pre-acquisition losses at IMN, Ostex and ADC. The future benefit of these losses will be applied first to reduce to zero any goodwill and other noncurrent intangible assets related to the acquisitions, prior to reducing our income tax expense. Also included in our domestic NOL carryforwards at December 31, 2004 was approximately $1.8 million 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. Furthermore, all domestic losses are subject to the Internal Revenue Service Code Section 382 limitation 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%. Section 382 imposes an annual limitation on the use of these losses to an amount equal to the value of the company at the time of the ownership change multiplied by the long term tax exempt rate. 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.

Off-Balance Sheet Arrangements

We had no material off-balance sheet arrangements as of December 31, 2004.

Contractual Obligations

The following table summarizes our principal contractual obligations as of December 31, 2004 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**	**2005**	**2006 2007**	**2008 2009**	**Thereafter**
			(in thousands)		
Long-term debt obligations(1)	$ 190,100	$ 88	$ 12	$ 40,000	$ 150,000
Capital lease obligations(2)	2,176	607	1,202	367	
Operating lease obligations(3)	68,089	6,377	12,121	9,227	40,364
Long-term and other liabilities(4)	4,654	570	2,392	1,692	
Minimum royalty obligations	100	20	40	40	
Purchase obligations capital expenditure	5,429	5,429			
Purchase obligations other(5)	35,154	35,154			
Contingent consideration(6)	1,500	1,500			
Total	$ 307,202	$ 49,745	$ 15,767	$ 51,326	$ 190,364

(1) See description of various financing arrangements in this section and note 6 of our consolidated financial statements included elsewhere in this annual report on Form 10-K.

(2) See note 7 of our consolidated financial statements included elsewhere in this annual report on Form 10-K.

(3) See note 10(a) of our consolidated financial statements included elsewhere in this annual report on Form 10-K.

(4) Included in long-term and other liabilities are primarily $1.5 million in technology license payment obligations and $3.0 million in pension obligations.

(5) Other purchase obligations relate to inventory purchases and other operating expense commitments.

(6) See note 4(a) of our consolidated financial statements included elsewhere in this annual report on Form 10-K. The payment of this amount is contingent upon the successful completion of a new product by ADC by December 31, 2005.

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, or GAAP. 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 for the year ended December 31, 2004 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 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.

In connection with the acquisition of the rapid diagnostics business from Abbott Laboratories in September 2003, we entered into a transition services agreement with Abbott, whereby Abbott would continue to distribute the acquired products sold under the TestPack brand for a period of up to 18 months. During the transition period, we recognize revenue on sales of the TestPack products when title transfers from Abbott to third party customers.

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 diagnostic products and vitamins and nutritional supplements 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 and consumer 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 $55.2 million, $46.2 million and $44.2 million, or 15%, 16% and 22% of net product sales in 2004, 2003 and 2002, respectively, which have 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 $61.3 million and $55.4 million, net of allowances for doubtful accounts of $2.4 million and $0.8 million, as of December 31, 2004 and 2003, respectively. The significant increase in the allowance for doubtful accounts in 2004 primarily resulted from the establishment of a specific reserve for a doubtful accounts receivable balance of $1.4 million associated with a private label customer that failed to perform under the terms of our agreement during the second quarter of 2004.

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 $60.1 million and $47.4 million, net of a provision for excess and obsolete inventory of $4.1 million and $2.1 million, as of December 31, 2004 and 2003, 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, 2004, the balances of property, plant and equipment, goodwill and other intangible assets, net of accumulated depreciation and amortization, were $66.8 million, $221.2 million and $118.5 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 accepted valuation methods. 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 $86.1 million and $135.1 million, respectively, as of December 31, 2004. As of September 30, 2004, 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 September 30, 2004, which could lead to significant impairment charges of goodwill in the future. No events or circumstances have occurred since our review as of September 30, 2004, 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, 2004, 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 $80.2 million as of December 31, 2004 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.

In accordance with SFAS No. 109, *Accounting for Income Taxes*, and SFAS No. 5, *Accounting for Contingencies*, we established reserves for tax contingencies that reflect our best estimate of the transactions and deductions that we may be unable to sustain or that we could be willing to concede as part of a broader tax settlement. We are currently undergoing routine tax examinations by various state and foreign jurisdictions. Tax authorities periodically challenge certain transactions and deductions we reported on our income tax returns. We do not expect the outcome of these examinations, either individually or in the aggregate, to have a material adverse effect on our financial position, results of operations, or cash flows.

In October 2004, the American Jobs Creation Act of 2004, or the AJCA, was signed into law. The AJCA contains a series of provisions, several of which are pertinent to our company. The AJCA creates a temporary incentive for U.S. multinational corporations to repatriate accumulated income abroad by providing an 85% dividends received deduction for certain dividends from controlled foreign corporations. It has been our company's practice to permanently reinvest all foreign earnings into foreign operations and we currently expect to continue to reinvest foreign earnings permanently into our foreign operations. Should we plan to repatriate any foreign earnings in the future, we will be required to establish an income tax expense and related tax liability on such earnings.

Legal Contingencies

In the section of this annual report on Form 10-K titled "Item 3. Legal Proceedings," we have reported on certain material pending legal proceedings. In addition, because of the nature of our business, we may from time to time be subject to commercial disputes, 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 commercial or personal injuries allegedly suffered and can include claims for punitive or other special damages. 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 do not accrue for potential losses on legal proceedings where our company is the defendant when we are not able to reasonably estimate 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 reasonably estimable and probable as the case progresses, in which case we will begin accruing for the expected loss.

Recently Issued Accounting Standards

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

In December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment,* or SFAS No. 123R. SFAS No. 123R addresses the accounting for transactions in which a company receives employee services in exchange for (a) equity instruments of the company or (b) liabilities that are based on the fair value of the company's equity instruments or that may be settled by the issuance of such equity instruments. It eliminates the ability to account for share-based compensation transactions using Accounting Principles Board, or APB, Opinion No. 25, *Accounting for Stock Issued to Employees*, and generally requires that such transactions be accounted for using a fair-value-based method. As

permitted by the current SFAS No. 123, *Accounting for Stock-Based* Compensation, we have been accounting for share-based compensation to employees using APB Opinion No. 25's intrinsic value method and, as such, we generally recognize no compensation cost for employee stock options. We are required to adopt SFAS No. 123R for the interim period beginning after June 15, 2005. We expect that the requirement to expense stock options and other equity interests that have been or will be granted pursuant to our equity incentive program will significantly increase our operating expenses and result in lower earnings per share. Based on the current outstanding unvested number of stock options, we expect to record non-cash compensation charges of approximately $2.7 million in the second half of 2005. The adoption of this statement will have no impact on our cash flows.

In December 2004, the FASB issued FASB Staff Position, or FSP, No. 109-1, *Application of FASB Statement No. 109, "Accounting for Income Taxes", to the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004*. FSP No. 109-1 states that the impact of the tax deduction on qualified production activities provided by the AJCA should be accounted for as a special deduction rather than a rate reduction. FSP No. 109-1 was effective immediately and had no impact on our 2004 consolidated financial statements.

In December 2004, the FASB issued FSP No. 109-2, *Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004*. FSP No. 109-2 grants a waiver to the SFAS No. 109 requirement to account for the impacts of new legislation in the period of enactment. FSP No. 109-2 was effective immediately and had no impact on our 2004 consolidated financial statements.

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

Certain Factors Affecting Future Results

The risks described below 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 any 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 56 of this report.

Our business has substantial indebtedness, which could, among other things, make it more difficult for us to satisfy our debt obligations, require us to use a large portion of our cash flow from operations to repay and service our debt or otherwise create liquidity problems, limit our flexibility to adjust to market conditions, place us at a competitive disadvantage and expose us to interest rate fluctuations.

We currently have, and we will likely continue to have, a substantial amount of indebtedness. As of December 31, 2004, we had approximately $192.3 million in aggregate principal indebtedness outstanding, of which $22.3 million is secured indebtedness, and $29.9 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 our $150 million in outstanding 8 3/4% senior subordinated notes, or the senior subordinated notes, we may incur additional indebtedness. During the fiscal years

ended December 31, 2004 and 2003, we recorded $22.1 million and $9.7 million, respectively, of interest expense related to our indebtedness, which included $4.2 million and $1.0 million, respectively, in non-cash interest primarily related to amortization of debt origination costs.

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;

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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. In particular, all acquisitions of other businesses, other than very small acquisitions, will require us to obtain our lenders' consent under our senior credit facility. We have been required to obtain, and have obtained, our lenders' consent under our senior credit facility in order to complete our acquisitions of the Wampole Division of MedPointe Inc., or Wampole, Ostex International, Inc., or Ostex, Applied Biotech, Inc., or ABI, and the rapid diagnostics business that we acquired from Abbott Laboratories, or the Abbott rapid diagnostics business as well as our pending acquisitions of Binax, Inc. and Ischemia Technologies, Inc.

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

As of December 31, 2004, we had approximately $20.1 million of indebtedness outstanding under our senior credit facility and approximately $29.9 million of additional borrowing capacity thereunder. The agreements governing this facility 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 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 our senior credit facility 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.

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, which could limit our opportunity to enter into a change of control transaction.

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 10% subordinated notes and, if the lenders accelerate the debt under our senior credit facility, the indenture governing the senior subordinated notes, and may result in the acceleration of any of our other indebtedness outstanding at the time. As a result, if we do not have enough cash to repay all of our indebtedness or to repurchase all of the senior subordinated notes, we may be limited in the change of control transactions that we may pursue.

Our acquisitions may not be profitable, and the integration of these businesses may be costly and difficult and may cause disruption to our business.

We have, since commencing activities in November 2001, acquired and attempted to integrate into our operations Unipath Limited and its associated companies and assets, or the Unipath business, IVC Industries, Inc. (now doing business as Inverness Medical Nutritionals Group, or IMN), Wampole, Ostex, ABI and the Abbott rapid diagnostics business and we intend to consummate our acquisition of Binax and Ischemia Technologies during March 2005. We have also made a number of smaller acquisitions. 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 assets into our existing businesses. However, the successful integration of independent businesses or assets 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. Additionally, the costs associated with the integration of our acquisitions, including our costs associated with the integration of the operations of Ostex and ABI and the Abbott rapid diagnostics business, can be substantial. To the extent that we incur integration costs that are not anticipated when we finance our acquisitions, these unexpected costs could adversely impact our liquidity or force us to borrow additional funds. Ultimately, the value of any business or asset that we have acquired may not be greater than or equal to its purchase price.

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;
- 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 and/or other intangible assets that we have recorded in connection with our acquisitions of other businesses become 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 business, 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 reported 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 products and some of our 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 and non-digital e.p.t pregnancy tests for Pfizer in connection with our supply arrangements with Pfizer for these products. 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.

We may experience manufacturing problems or delays, which could result in decreased revenues or increased costs.

Many of our manufacturing 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 diagnostic 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 numerous third parties to supply production materials and in some cases there may not be alternative sources immediately available.

In addition, we currently rely on nine significant third-party manufacturers, as well as numerous other less significant manufacturers, to produce many of our professional diagnostic products and certain components of our consumer diagnostic products, including products in development. In addition, certain of the products acquired as part of the Abbott rapid diagnostics business 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, 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 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 cannot 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.

The factors listed above, as well as manufacturing or distribution problems, or other factors beyond our control, could delay new product 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 new products are launched.

We may experience difficulties that may delay or prevent us from completing our plans to centralize our U.S. consumer products packaging and distribution facilities, and our plans to manufacture certain products in China.

We have commenced operations of our centralized U.S. packaging and distribution facility serving our consumer diagnostic and vitamins and nutritional supplements segments and begun to transition the manufacture of certain products to China. We may not complete our plans with respect to these operations in the time projected, or at all, if we are unable to develop or finalize the necessary third party relationships; acquire the required facilities, equipment or materials; or obtain any necessary consents or approvals. In addition, even if we do succeed in developing these new operations on schedule, operational problems, or other factors beyond our control, may prevent or delay us from recognizing cost savings, margin improvements or other benefits that we may expect.

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 or our processes 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, delay or withdraw pre-market clearances or other regulatory approvals 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.

In March 2005, our ABI subsidiary was informed by the FDA that, based on inspectional findings that included data integrity and design control issues, ABI has become subject to the FDA's Application Integrity Policy. As a result, the FDA will defer the review of any pending or future applications made by ABI until the FDA determines that ABI has resolved these issues. ABI currently has no applications pending. At this time ABI is not restricted with regard to introducing new tests outside of the United States, or from selling products in the United States based on any existing 510(k)s. It is our understanding that the FDA action applies only to ABI and does not otherwise restrict our ability, or the ability of our other subsidiaries, to submit applications to the FDA or commercialize products. However, the scope and the impact are uncertain, and may have a negative effect on our future sales and profits.

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, and 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 brand name 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 aggregate sales of all of our brand name nutritional products, including, among others, Ferro-Sequels, Stresstabs, Protegra, Posture, SoyCare, ALLBEE, and Z-BEC, have declined each year since 1998 through the year 2004,except in 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. As a result we do not expect significant sales growth of our existing brand name nutritional products and we may experience further declines in overall sales of our brand name nutritional products in the future.

Our sales of specific vitamins and nutritional supplements could be negatively impacted by media attention or other news developments that challenge the safety and effectiveness of those specific vitamins and nutritional supplements.

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 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 material pending 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.

Because of the nature of our business, we may be subject at any particular time to commercial disputes, 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 commercial or personal injuries allegedly suffered and can include claims for punitive or other special damages. An adverse ruling or rulings in one or more such lawsuits could, individually or in the aggregate, have a material adverse effect on our sales, operations or financial performance. In addition, we aggressively defend our patent and other intellectual property rights. This often involves bringing infringement or other commercial claims against third parties, such as our litigation against Acon Laboratories. These suits can be expensive and result in counterclaims challenging the validity of our patents and other rights. We cannot assure you that these lawsuits or any future lawsuits relating to our businesses will not have a material adverse effect on us.

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

For the years ended December 31, 2004 and 2003, approximately two-thirds of our net product sales, respectively, were derived from our consumer products business, which consists of our consumer diagnostic products and vitamin and nutritional supplements segments. These 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 relatively high, especially in our vitamin and nutritional supplements segment where two customers currently account for almost 65% of sales. 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 customer relationships and likely lose customers. Additionally, if we are unable to maintain close working relationships with our customers, sales of all of our products and our ability to successfully launch new products could suffer. 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 diagnostic products segment 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 with Pfizer Inc., through one of its wholly-owned subsidiaries, Pfizer purchases its non-digital e.p.t pregnancy tests from us through 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.

Because sales of our private label nutritional supplements are generally made at low margins, the profitability of these products may suffer significantly as a result of relatively small increases in raw material or other manufacturing costs.

Sales of our private label nutritional supplements, which for the years ended December 31, 2004 and 2003, provided approximately 17% and 20%, respectively, of our net product sales, generate low profit margins. We rely on our ability to efficiently mass produce nutritional supplements in order to make meaningful profits from these products. 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. The resulting margin erosion in our nutritionals business has resulted in a reduction in our overall gross margin and contributed to our losses in 2004, as compared to our income in 2003.

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

Approximately 40% and 36% of our net revenues were generated from outside the United States for the year ended December 31, 2004 and 2003, respectively. 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. Four of our manufacturing facilities are outside the United States, in Bedford, England, Galway, Ireland, Shanghai, China and Yavne, Israel. We have also announced plans to consolidate much of our cardiovascular related research and development in Scotland and ultimately to establish a significant manufacturing operation there. Approximately 40% and 36% of our net revenues were generated from outside the United States for the year ended December 31, 2004 and 2003, respectively. Our Clearblue pregnancy test product sales have historically been much stronger outside the United States, with 74% of net product sales of these products coming from outside the United States during the year ended December 31, 2004. In addition, the Abbott rapid diagnostics business, which we acquired on September 30, 2003, generates a majority of its sales outside 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.

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 Inverness Medical Technology, Inc., or IMT, we agreed not to compete with IMT and Johnson & Johnson in the field of diabetes through 2011. 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.

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, independent registered public accounting firm, our consolidated financial statements as of December 31, 2001 and 2000, to the extent included in this report or in previously filed reports or registrations 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.

Because our operating results may fluctuate from quarter to quarter, it may be difficult for us or our investors to predict our future performance by viewing our historical operating results.

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, ABI in August 2003 and the Abbott rapid diagnostics business 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.

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

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

In addition, our share price may be volatile due to our operating results, as well as factors beyond our control. During 2004, the sales price of our common stock ranged from $14.75 to $25.50, and during 2003, the sales price of our common stock ranged from $13.40 to $27.50. It is possible that in

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

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

Anti-takeover provisions in our organizational documents and Delaware law may limit the ability of our stockholders to control our policies and effect a change of control of our company and prevent attempts by our stockholders to replace or remove our current management, which may not be in your best interests.

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

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

our certificate of incorporation provides for the removal of a director only with cause and by the affirmative vote of the holders of 75% or more of the shares then entitled to vote at an election of our directors; and

our bylaws require advance written notice of stockholder proposals and director nominations.

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

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

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

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 or arising out of ABI's subjection to the FDA's Application Integrity Policy, 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 ABI and the Abbott rapid diagnostics business, 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, the Public Company Accounting Oversight 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 or our 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, 2004, our short-term investments approximated market value.

At December 31, 2004, we had revolving lines of credit available to us of up to $50.0 million in the aggregate under our primary senior credit facility, against which $20.1 million was outstanding. 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 credit 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 2.75% to 3.75% or 1.50% to 2.50%, respectively, depending on the quarterly adjustments that are based on our consolidated financial performance.

As of December 31, 2004, the LIBOR and Index rates applicable under our primary senior credit facility were 2.40% and 5.25%, respectively. Assuming no changes in our leverage ratio, which would affect the margin of the interest rate under the senior credit agreement, the effect of interest rate fluctuations on outstanding borrowings under the revolving lines of credit as of December 31, 2004 over the next twelve months is quantified and summarized as follows:

(in thousands)	**Interest Expense Increase**
Interest rates increase by 1 basis point	$ 201
Interest rates increase by 2 basis points	$ 402

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. During 2004, the net impact of foreign currency changes on transactions was a loss of $0.7 million. Generally, we do not use derivative financial instruments or other financial instruments with original maturities in excess of three months 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 gross margin on total net product sales was 39.1% in 2004. If the U.S. dollar had been stronger by 1%, 5% or 10%, compared to the actual rates during 2004, our gross margin on total net product sales would have been 39.4%, 40.0% and 40.8%, 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:

(in thousands)	Approximate Decrease in Net Revenue	Approximate Increase in Net Loss
If during 2004, the U.S. dollar was stronger by:		
1%	$ 1,013	$ 79
5%	5,064	396
10%	10,128	791

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements and supplementary data, except for selected quarterly financial data which are summarized below, are listed under Item 15(a) and have been filed as part of this report on the pages indicated.

We restated our previously issued consolidated financial statements as of and for the years ended December 31, 2003 and for the first three quarters of 2004 to correct an error in the calculation of the provisions for income taxes and the related deferred tax accounts. We should have reported gross, certain deferred tax liabilities associated with temporary differences related to differing tax and book bases of goodwill and other intangible assets. As a result, we have recorded an additional valuation allowance against the deferred tax assets associated with certain net operating loss carry forwards. The correction of this error resulted in incremental non-cash provisions of income taxes in the amount of $0.4 million in each of the first three quarters of 2003 and $0.7 million in the fourth quarter of 2003 and in each of the first three quarters of 2004. In addition, we revised our purchase price allocation in connection with our acquisition of the Abbott business on September 30, 2003 to attribute $5.7 million to customer related intangible assets acquired in the acquisition. We have also recorded and commenced to amortize as of the date of the acquisition $11.3 million of other assets acquired from Abbott, the amortization of which was insignificant to our financial results. Goodwill generated in connection with the acquisition of the Abbott business was reduced by these amounts. The impact of this revision of the purchase price allocation was to increase amortization expense by $0.9 million in the fourth quarter of 2003 and in each of the first three quarters of 2004.

Selected quarterly financial data for 2004 and 2003 are summarized as follows:

	2004				2003			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
	(restated) (2)	(restated) (3)	(restated) (4)	(5)	(restated)	(restated) (6)	(restated) (7)	(restated) (8)
	(in thousands, except per share data)							
Net revenue	$ 90,701	$ 88,727	$ 97,505	$ 99,977	$ 65,102	$ 65,717	$ 72,393	$ 93,500
Gross profit	36,909	35,004	38,334	39,115	29,830	28,674	31,491	38,546
Net (loss) income	(3,671)	(7,057)	(2,262)	(1,248)	1,912	5,221	1,281	1,146
Net (loss) income available to common stockholders(1):								
Basic	(4,420)	(7,057)	(2,262)	(1,248)	1,739	5,080	1,138	645
Diluted	(4,420)	(7,057)	(2,262)	(1,248)	1,739	5,229	1,138	645
Net (loss) income per common share(1):								
Basic	$ (0.23)	$ (0.36)	$ (0.11)	$ (0.06)	$ 0.13	$ 0.36	$ 0.07	$ 0.03
Diluted	$ (0.23)	$ (0.36)	$ (0.11)	$ (0.06)	$ 0.11	$ 0.31	$ 0.06	$ 0.03

(1) Net (loss) income available to common stockholders and basic and diluted net (loss) income per common share are computed as consistent with the annual per share calculations described in notes 2(k) and 11 of our consolidated financial statements included elsewhere in this annual report on Form 10-K.

(2) Included in net loss in the first quarter of 2004 is a charge of $3.5 million in interest expense representing the write-off of deferred financing costs and prepayment fees and penalties related to the repayment of borrowings under our primary senior credit facility and certain subordinated notes with the proceeds from our $150.0 million bond offering in February 2004.

(3) Included in net loss in the second quarter of 2004 is an additional charge of $0.3 million in interest expense representing the write-off of financing costs related to the repayment of borrowings under our primary senior credit facility with the proceeds from our $150.0 million bond offering in February 2004 and the establishment of a specific reserve for potential bad debt and unsaleable inventory totaling $1.5 million associated with a customer that failed to perform under the terms of our agreement and is currently subject to legal action.

(4) Included in net loss in the third quarter of 2004 is a $1.7 million restructuring charge covering all expected severance, early retirement and outplacement services arising from a completed plan of termination at our manufacturing facility in Bedford, England.

(5) Included in net loss in the fourth quarter of 2004 are (i) $0.9 million in release of a pre-acquisition legal contingency reserve upon reaching and signing a settlement agreement, and (ii) $0.5 million in litigation settlement gain.

(6) Included in 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.

(7) Included in net income in the third quarter of 2003 is a one-time gain of $0.7 million as a result of insurance recovery of legal costs previously incurred.

(8) Included in net income in the fourth quarter of 2003 are (i) reversals of allowances for returns and trade spending of specific products aggregating $0.9 million, 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.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Management's 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 our 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 our disclosure controls and procedures were effective at that time. 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.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) under the Securities Exchange Act of 1934, as amended. Our company's internal control over financial reporting is a process designed under the supervision of the CEO and CFO to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

(i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;

(ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of our company are being made only in accordance with authorizations of our management and directors; and

(iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of assets that could have a material effect on the financial statements.

There are inherent limitations in the effectiveness of any internal control, including the possibility of human error and the circumvention or overriding of controls. Accordingly, even effective internal controls can provide only reasonable assurances with respect to financial statement preparation. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the design and effectiveness of our company's internal control over financial reporting as of December 31, 2004. In making this assessment, management used the criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In performing this assessment, management considered the impact of its February 8, 2005 decision to restate certain previously issued financial statements in order to revise the purchase price allocation performed in connection with our acquisition of the Abbott rapid diagnostics business on September 30, 2003 to attribute value to customer related intangible assets acquired in the acquisition. Management also considered the impact of its December 2, 2004 decision to restate certain previously issued financial statements in order to correct an error in the application of GAAP related to the calculation of its provision for income taxes and the related deferred taxes. The Public Company Accounting Oversight Board's Auditing Standard No. 2 identifies a number of circumstances that are to be regarded as at least significant deficiencies and as strong indicators that a material weakness in internal control over financial reporting exists, including the restatement of previously issued financial statements to reflect the correction of a misstatement. Based on this guidance, management has concluded that, as a result of our need to restate previously issued financial statements as described above, a material weakness existed in our internal control over financial reporting as of December 31, 2004 and, to this extent, our internal control over financial reporting was not effective as of such date.

Management believes that it has remediated the material weakness in internal control over financial reporting by implementing the following policies and procedures:

(i) In connection with improving our accounting for business combinations in the future, we have instituted a policy that requires all customer relationships acquired in a business combination to be evaluated to determine if they have independent value regardless of whether the terms of the ongoing relationship are arms length; and

(ii) In connection with improving our tax accounting controls, we implemented a control in the area of tax accounting requiring the independent review on a quarterly basis of such tax accounting by an international accounting and auditing firm other than our auditors.

As indicated in its Attestation Report included below, BDO Seidman, LLP, the independent registered public accounting firm that audited the financial statements included in this report, has attested to our management's assessments regarding the design and effectiveness of our internal control over financial reporting as of December 31, 2004.

Attestation Report of the Registered Public Accounting Firm

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

We have audited management's assessment, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting appearing under Item 9a, that Inverness Medical Innovations, Inc. and subsidiaries did not maintain effective internal control over financial reporting as of December 31, 2004, because of the effect of the material weakness identified in management's assessment, based on the criteria established in *Internal Control Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Inverness Medical Innovations, Inc. and subsidiaries' management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operation effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject

to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

A material weakness is a control deficiency, or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. The following material weaknesses were identified and included in management's assessment:

As a result of the restatement of its financials statements in February 2005, the Company identified a material weakness in its internal controls related to the application of accounting principles generally accepted in the United States of America in connection with the identification of the independent value of customer relationships regardless of whether the terms of the ongoing relationship were at arms length.

In addition, as a result of the December 2004 decision to restate certain previously issued financial statements in order to correct an error in the application of accounting principles generally accepted in the United States of America related to the calculation of its provision for income taxes and related deferred taxes, the Company identified a material weakness in its internal controls related to the application of income tax accounting principles generally accepted in the United States of America.

These material weaknesses were considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2004 financial statements, and this report does not affect our report dated March 14, 2005 on those financial statements, which expressed an unqualified opinion.

In our opinion, management's assessment that Inverness Medical Innovations, Inc. and subsidiaries did not maintain effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, is based on the criteria established in *Internal Control Integrated Framework* issued by COSO. Also, in our opinion, because of the effect of the material weaknesses described above on the achievement of the objectives of the control criteria, Inverness Medical Innovations, Inc. and subsidiaries has not maintained effective internal control over financial reporting as of December 31, 2004, based on the criteria established in *Internal Control Integrated Framework* issued by the COSO.

BDO Seidman, LLP

Boston, MA
March 14, 2005

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 2004 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting except that, as discussed above, we implemented a control in the area of tax accounting requiring the independent review on a quarterly basis of such tax accounting by an international accounting and auditing firm other than our auditors. This control was implemented during the fourth quarter and effective as of December 31, 2004.

ITEM 9B. OTHER INFORMATION

Not applicable.

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 2005 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 and related stockholder matters 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. FINANCIAL STATEMENT SCHEDULES AND EXHIBITS

(a)

1. Financial Statements.

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

2. Financial Statement Schedules.

All schedules for which provision is made in the applicable accounting regulation of the Securities and Exchange Commission have been omitted because they are inapplicable or the required information is shown in the consolidated financial statements, or notes thereto, included herein.

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 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)

2.3 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)

2.4 Agreement and Plan of Merger, dated February 8, 2005, by and among Inverness Medical Innovations, Inc., a Delaware corporation to be formed as a wholly-owned subsidiary of Inverness Medical Innovations, Inc., Binax, Inc., Roger N. Piasio and Myron C. Hamer, and Roger N. Piasio, as stockholder representative (incorporated by reference to Exhibit 99.1 to the Company's Current Report of Form 8-K dated February 9, 2005)

2.5 Agreement and Plan of Merger, dated February 15, 2005, by and among Inverness Medical Innovations, Inc., a Delaware corporation to be formed as a wholly-owned subsidiary of Inverness Medical Innovations, Inc., and Ischemia Technologies, Inc. (incorporated by reference to Exhibit 99.1 to the Company's current report on form 8-K dated February 15, 2005)

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	Indenture, dated as of February 10, 2004, between Inverness Medical Innovations, Inc., the Guarantors named therein and U.S. Bank Trust National Association (incorporated by reference to Exhibit 4.3 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2004)
4.3	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 (incorporated by reference to Exhibit 4.4 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2004)
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 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)

10.18 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)

10.19 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)

10.20 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)

10.21 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)

10.22 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)

10.23 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))

10.24 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)

10.25 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)

10.26 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)

10.27 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)

10.28 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))

10.29 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)

10.30 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)

10.31 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)

10.32 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)

10.33 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)

10.34 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)

10.34 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 (incorporated by reference to Exhibit 10.41 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2004)

10.36 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 (incorporated by reference to Exhibit 10.42 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2004)

10.37 Third Amendment and Consent to Second Amended and Restated Credit Agreement and Consent to Intercreditor Agreement, dated as of January 20, 2004, by and among Inverness Medical Innovations, Inc., Wampole Laboratories, LLC., 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 Lender, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as documentation agent and co-syndication agent, and UBS Securities, LLC, as co-syndication agent (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, as amended, for the period ended March 31. 2004)

10.38 Fourth Amendment to Second Amended and Restated Credit Agreement and Amendment to Loan Documents, dated as of February 5, 2004 by and among Inverness Medical Innovations, Inc., Wampole Laboratories, LLC, 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 documentation agent and co-syndication agent, and UBS Securities, LLC, as co-syndication agent (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, as amended, for the period ended March 31. 2004)

10.39 Fifth Amendment and Consent to Second Amended and Restated Credit Agreement and Amendment to Post-Closing Letter, dated as of April 28, 2004 by and among Inverness Medical Innovations, Inc., Wampole Laboratories, LLC, 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 documentation agent and co-syndication agent, and UBS Securities, LLC, as co-syndication agent (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, as amended, for the period ended March 31. 2004)

10.40 Sixth Amendment and Consent to Second Amended and Restated Credit Agreement, dated as of June 1, 2004, by and among General Electric Capital Corporation, as Agent and lender, Inverness Medical Innovations, Inc., Wampole Laboratories, LLC, Inverness Medical (UK) Holdings Limited, the other Credit Parties signatory thereto, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as documentation agent, co-syndication agent and Lender, UBS Securities, LLC, as co-syndication agent and lender, and the lenders signatory thereto from time to time. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, as amended, for the period ended June 30, 2004)

10.41 Seventh Amendment and Consent to Second Amended and Restated Credit Agreement, dated as of July 27, 2004 by and among General Electric Capital Corporation, as Agent and lender, Inverness Medical Innovations, Inc., Wampole Laboratories, LLC, Inverness Medical (UK) Holdings Limited, the other Credit Parties signatory thereto, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as documentation agent, co-syndication agent and Lender, UBS Securities, LLC, as co-syndication agent and lender, and the lenders signatory thereto from time to time. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, as amended, for the period ended June 30, 2004)

*10.42 Eighth Amendment and Consent to Second Amended and Restated Credit Agreement, dated as of December 20, 2004 by and among General Electric Capital Corporation, as Agent and lender, Inverness Medical Innovations, Inc., Wampole Laboratories, LLC, Inverness Medical (UK) Holdings Limited, the other Credit Parties signatory thereto, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as documentation agent, co-syndication agent and Lender, UBS Securities, LLC, as co-syndication agent and lender, and the lenders signatory thereto from time to time.

*10.43 Ninth Amendment, Consent and Waiver to Second Amended and Restated Credit Agreement, dated as of January 19, 2005 by and among General Electric Capital Corporation, as Agent and lender, Inverness Medical Innovations, Inc., Wampole Laboratories, LLC, Inverness Medical (UK) Holdings Limited, the other Credit Parties signatory thereto, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as documentation agent, co-syndication agent and Lender, UBS Securities, LLC, as co-syndication agent and lender, and the lenders signatory thereto from time to time.

*10.44 Tenth Amendment and Consent to Second Amended and Restated Credit Agreement, dated as of January 31, 2005 by and among General Electric Capital Corporation, as Agent and lender, Inverness Medical Innovations, Inc., Wampole Laboratories, LLC, Inverness Medical (UK) Holdings Limited, the other Credit Parties signatory thereto, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as documentation agent, co-syndication agent and Lender, UBS Securities, LLC, as co-syndication agent and lender, and the lenders signatory thereto from time to time.

*10.45	Eleventh Amendment and Consent to Second Amended and Restated Credit Agreement, dated as of February 23, 2005 by and among General Electric Capital Corporation, as Agent and lender, Inverness Medical Innovations, Inc., Wampole Laboratories, LLC, Inverness Medical (UK) Holdings Limited, the other Credit Parties signatory thereto, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as documentation agent, co-syndication agent and Lender, UBS Securities, LLC, as co-syndication agent and lender, and the lenders signatory thereto from time to time.
10.46	Commercial Lease, dated August 1, 1998, by and between The Chang Family Trust and Applied Biotech, Inc. (incorporated by reference to Exhibit 10.43 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2004)
10.47	Amendment to Commercial Lease, dated April , 2003, by and between The Chang Family Trust and Applied Biotech, Inc. (incorporated by reference to Exhibit 10.44 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2004)
+10.48	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+ (incorporated by reference to Exhibit 10.45 to Amendment No. 2 to the Company's Annual Report on Form 10-K for the year ended December 31, 2004)
10.49	First Amendment to Subordinated Promissory Notes, dated as of November 14, 2003 (incorporated by reference to Exhibit 10.46 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2004)
14.50	Inverness Medical Innovations Business Conduct Guidelines (incorporated by reference to Exhibit 14.1 to the Company's Annual Report on Form 10-K, as amended, for the year ended December 31, 2004)
*21.1	List of Subsidiaries of the Company as of March 15, 2005
*23.1	Consent of BDO Seidman, LLP
*31.1	Certification by Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act
*31.2	Certification by Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act
*32.1	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act

* Filed herewith.

\+ We have omitted portions of this exhibit which have been granted confidential treatment.

SIGNATURES

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

INVERNESS MEDICAL INNOVATIONS, INC.

Date: March 16, 2005 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 Ron Zwanziger	Chief Executive Officer, President and Director (Principal Executive Officer)	March 16, 2005
/s/ CHRISTOPHER J. LINDOP Christopher J. Lindop	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 16, 2005
/s/ ERNEST A. CARABILLO, JR. Ernest A. Carabillo, Jr.	Director	March 16, 2005
/s/ CAROL R. GOLDBERG Carol R. Goldberg	Director	March 16, 2005
/s/ ROBERT P. KHEDERIAN Robert P. Khederian	Director	March 16, 2005
/s/ JOHN F. LEVY John F. Levy	Director	March 16, 2005
/s/ JERRY MCALEER Jerry McAleer	Director	March 16, 2005
/s/ JOHN A. QUELCH John A. Quelch	Director	March 16, 2005
/s/ DAVID SCOTT David Scott	Director	March 16, 2005
/s/ PETER TOWNSEND	Director	March 16, 2005

Signature	Title	Date
Peter Townsend		
/s/ ALFRED M. ZEIEN	Director	March 16, 2005
Alfred M. Zeien		

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity and comprehensive income (loss), and cash flows for each of the three years in the period ended December 31, 2004. 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.

We conducted our audits in accordance with the Public Company Accounting Oversight Board (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 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, 2004 and 2003, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2004, 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 to reverse a foreign currency gain recorded in 2002, to record certain deferred tax liabilities associated with temporary differences related to differing book and tax bases of goodwill and other intangible assets in 2002 and 2003, to record adjustments related to sales incentive allowances in 2003 and to revise the purchase price allocation in connection with the acquisition of the rapid diagnostics business from Abbott Laboratories in 2003.

In 2002, the Company adopted the accounting required pursuant to Statement of Financial Accounting Standards ("SFAS") SFAS No. 142, *Goodwill and Other Intangible Assets.* The 2001 consolidated financial statements have been adjusted to disclose the effect of adjusting the statement of operations to exclude goodwill amortization for 2001, as required by SFAS No. 142.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO") and our report dated March 14, 2005 expressed an unqualified opinion on management's assessment on the effectiveness of internal control over financial reporting and an adverse opinion on the effectiveness of internal control over financial reporting because of the existence of a material weakness.

BDO Seidman, LLP

Boston, Massachusetts
March 14, 2005

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	2004	2003	2002
		(restated)	(restated)
Net product sales	$ 368,351	$ 286,984	$ 200,399
License revenue	8,559	9,728	6,405
Net Revenue	376,910	296,712	206,804
Cost of sales	227,548	168,171	114,653
Gross profit	149,362	128,541	92,151
Operating expenses:			
Research and development	31,954	24,280	14,471
Sales and marketing	57,957	52,504	39,544
General and administrative	52,707	35,452	28,066
Charge related to asset impairment (Note 5)			12,682
Stock-based compensation (1) (Note 12(c))		447	10,625
Total operating expenses	142,618	112,683	105,388
Operating income (loss)	6,744	15,858	(13,237)
Interest expense, including amortization of discounts (Note 6)	(22,114)	(9,711)	(15,069)
Other income, net	3,407	6,441	9,114
(Loss) income before income taxes	(11,963)	12,588	(19,192)
Provision for income taxes	2,275	3,028	3,443
(Loss) income before cumulative effect of a change in accounting principle	(14,238)	9,560	(22,635)
Cumulative effect of a change in accounting principle (Note 5)			(12,148)
Net (loss) income	$ (14,238)	$ 9,560	$ (34,783)
(Loss) income available to common stockholders basic and diluted (Note 11):			
(Loss) income before cumulative effect of a change in accounting principle	$ (14,987)	$ 8,602	$ (34,583)
Net (loss) income	$ (14,987)	$ 8,602	$ (46,731)
(Loss) income per common share basic (Notes 2(k) and 11):			
(Loss) income before cumulative effect of a change in accounting principle	$ (0.75)	$ 0.55	$ (3.48)
Net (loss) income	$ (0.75)	$ 0.55	$ (4.70)
(Loss) income per common share diluted (Notes 2(k) and 11):			
(Loss) income before cumulative effect of a change in accounting principle	$ (0.75)	$ 0.49	$ (3.48)

	2004	2003	2002
Net (loss) income	$ (0.75)	$ 0.49	$ (4.70)
Weighted average shares basic	19,969	15,711	9,940
Weighted average shares diluted	19,969	17,490	9,940

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

Research and development	$	$ 87	$ 37
Sales and marketing			26
General and administrative		360	10,562
Total stock-based compensation	$	$ 447	$ 10,625

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,	
	2004	**2003**
		(restated)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 16,756	$ 24,622
Accounts receivable, net of allowances of $9,359 and $7,492 at December 31, 2004 and 2003, respectively	61,347	55,418
Inventories	60,143	47,423
Deferred tax assets	2,819	1,178
Prepaid expenses and other current assets	9,601	10,599
Total current assets	150,666	139,240
Property, plant and equipment, net	66,780	57,773
Goodwill	221,155	216,733
Other intangible assets with indefinite lives	50,542	46,719
Core technology and patents, net	40,327	37,942
Other intangible assets, net	27,680	32,679
Deferred financing costs, net, and other non-current assets	9,156	7,457
Deferred tax assets	872	1,456
Total assets	$ 567,178	$ 539,999
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 88	$ 14,055
Current portion of capital lease obligations	467	457
Accounts payable	32,345	38,006
Accrued expenses and other current liabilities	51,886	41,122
Total current liabilities	84,786	93,640
Long-term liabilities:		
Long-term debt, net of current portion	189,268	159,838
Capital lease obligations, net of current portion	1,401	1,831
Deferred tax liabilities	12,596	9,118
Other long-term liabilities	4,446	3,307
Total long-term liabilities	207,711	174,094
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, 2004 and 2003		
Outstanding none at December 31, 2004 and 208 shares at December 31, 2003		6,185
Stockholders' equity:		

	December 31,	
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 20,711 shares at December 31, 2004 and 19,640 shares at December 31, 2003	21	20
Additional paid-in capital	359,582	341,703
Notes receivable from stockholders	(14,691)	(14,691)
Accumulated deficit	(87,752)	(72,765)
Accumulated other comprehensive income	17,521	11,813
Total stockholders' equity	274,681	266,080
Total liabilities and stockholders' equity	$ 567,178	$ 539,999

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)
						(restated)	(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					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(h))			(9,600)					(9,600)	
Warrants issued with subordinated debt (Note 6(c))			1,502					1,502	
Fair value of assumed and issued fully-vested stock options related to acquisition of IVC Industries, Inc. (Note 4(f))			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						(34,783)		(34,783)	(34,783)

	Common Stock								
Total comprehensive loss									$ (29,966)
BALANCE, DECEMBER 31, 2002	14,907	$ 15	$ 251,457	$ (14,691)	$ (48)	$ (81,368)	$ 6,484	$ 161,849	

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)	$ (81,368)	$ 6,484	$ 161,849	
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(d))			1,752					1,752	
Stock-based compensation related to grants of common stock options			399					399	
Amortization of deferred compensation					48			48	
Other (Note 13)							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						9,560		9,560	9,560
Total comprehensive income									$ 14,889
BALANCE, DECEMBER 31, 2003	19,640	$ 20	$ 341,703	$ (14,691)	$	$ (72,765)	$ 11,813	$ 266,080	

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	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity	Comprehensive Income (Loss)
					(restated)	(restated)	(restated)	
BALANCE, DECEMBER 31, 2003	19,640	$ 20	$ 341,703	$ (14,691)	$ (72,765)	$ 11,813	$ 266,080	
Issuance of common stock in connection with acquisitions, net of issuance costs of $88	156		2,914				2,914	$
Exercise of common stock options and warrants	153		1,998				1,998	
Conversion of series A redeemable convertible preferred stock to common stock (Note 12(b))	416	1	6,933		(739)		6,195	
Redemption interest related to series A redeemable convertible preferred stock (Note 12(b))					(10)		(10)	
Conversion of convertible subordinated promissory notes to common stock (Note 6(d))	346		6,034				6,034	
Other (Note 13)						33	33	33
Pension liability adjustment (Note 8(b))						434	434	434
Changes in cumulative translation adjustment						5,241	5,241	5,241
Net loss					(14,238)		(14,238)	(14,238)
Total comprehensive loss								$ (8,530)
BALANCE, DECEMBER 31, 2004	20,711	$ 21	$ 359,582	$ (14,691)	$ (87,752)	$ 17,521	$ 274,681	

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)

	2004	2003	2002
		(restated)	(restated)
Cash Flows from Operating Activities:			
Net (loss) income	$ (14,238)	$ 9,560	$ (34,783)
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Interest expense related to amortization of noncash original issue discount, noncash beneficial conversion feature and deferred financing costs	4,929	1,565	7,499
Noncash (income) expense related to interest rate swap agreement	(695)	(528)	1,223
Noncash stock-based compensation expense		447	10,625
Noncash value on settlement of litigation	(495)		
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	23,500	16,435	10,308
Deferred income taxes	2,232	812	786
Other noncash items	(36)		354
Changes in assets and liabilities, net of acquisitions:			
Accounts receivable, net	(4,095)	(9,592)	1,227
Inventories	(10,512)	(2,054)	(2,090)
Prepaid expenses and other current assets	2,116	(4,102)	468
Accounts payable	(6,897)	6,715	8,847
Accrued expenses and other current liabilities	12,130	(9,457)	(10,558)
Other non-current liabilities	356		
Net cash provided by operating activities	8,295	9,801	9,136
Cash Flows from Investing Activities:			
Purchases of property, plant and equipment	(20,389)	(11,135)	(6,077)
Proceeds from sale of property, plant and equipment	385	152	1,545
Cash paid for purchase of assets from Abbott Laboratories	(1,634)	(55,947)	
Cash paid for purchase of Applied Biotech, Inc., net of cash acquired	(530)	(14,042)	
Cash paid for purchase of Ostex International, Inc., net of cash acquired	(1,415)	(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	(256)	(535)	(7,112)
Cash paid for purchase of Unipath business, net of cash acquired	(50)	(649)	(2,832)
Cash paid for purchase of other businesses and intellectual property	(8,524)	(4,007)	
Loan to Ostex International, Inc.			(1,000)
(Increase) decrease in other assets	(1,889)	396	(560)
Net cash used in investing activities	(34,302)	(89,130)	(86,644)
Cash Flows from Financing Activities:			
Cash paid for financing costs	(5,671)	(4,533)	(3,975)
Proceeds from issuance of common stock, net of issuance costs	1,905	4,003	35,322
Proceeds from issuance of preferred stock, net of issuance costs			20,567
Net (repayment) proceeds under revolving line of credit	(30,830)	19,331	2,649
Proceeds from issuance of senior subordinated notes	150,000		
Proceeds from borrowings under notes payable		57,621	84,421
Repayments of notes payable	(97,830)	(5,785)	(82,240)

	2004	2003	2002
Principal payments of capital lease obligations	(477)	(651)	(494)
Net cash provided by financing activities	17,097	69,986	56,250
Foreign exchange effect on cash and cash equivalents	1,044	3,297	(98)
Net decrease in cash and cash equivalents	(7,866)	(6,046)	(21,356)
Cash and cash equivalents, beginning of year	24,622	30,668	52,024
Cash and cash equivalents, end of year	$ 16,756	$ 24,622	$ 30,668

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)

	2004	2003 (restated)	2002
Supplemental Disclosure of Cash Flow Information:			
Interest paid	$ 13,535	$ 9,091	$ 4,519
Taxes paid	$ 3,067	$ 1,447	$ 2,728
Supplemental Disclosure of Noncash Activities:			
On September 30, 2003, we acquired certain assets from Abbott Laboratories (Note 4 (b))			
Inventories	$	$ 380	$
Property, plant and equipment		1,310	
Intangible assets	94	93,297	
Accrued acquisition costs	1,540	(1,540)	
Cash paid for purchase of certain assets from Abbott Laboratories	(1,634)	(55,947)	
Fair value of common stock issued	$	$ 37,500	$
On August 27, 2003, we acquired Applied Biotech, Inc. (Note 4 (c))			
Accounts receivable	$	$ 6,368	$
Inventories		6,056	
Property, plant and equipment	(1,051)	5,352	
Intangible assets	1,143	15,615	
Other assets		117	
Accounts payable and accrued expenses	(92)	(4,669)	
Accrued acquisition costs	530	(530)	
Cash paid for purchase of Applied Biotech, Inc., net of cash acquired	(530)	(14,042)	
Fair value of common stock issued	$	$ 14,267	$
On June 30, 2003, we acquired Ostex International, Inc. (Note 4(d))			
Accounts receivable	$ 25	$ 1,264	$
Inventories	(39)	506	
Property, plant and equipment	(25)	629	
Intangible assets	352	31,468	
Other assets	(13)	177	
Accounts payable and accrued expenses	(62)	(1,891)	
Long-term debt		(2,875)	
Accrued acquisition costs	1,177	(2,086)	
Cash paid for purchase of Ostex International, Inc., net of cash acquired	(1,415)	(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	$

	2004	2003	2002
On September 20, 2002, we acquired the Wampole Division from MedPointe Inc. (Note 4(e))			
Accounts receivable	$	$ (451)	$ 8,737
Inventories		(75)	4,924
Other current assets		1	967
Property and equipment		156	2,061
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)
	$	$	$

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)

	2004	2003	2002
On March 19, 2002, we acquired IVC Industries, Inc. (Note 4(f)			
Accounts receivable	$	$	$ 4,716
Inventories			9,832
Property and equipment			23,016
Other assets			1,755
Accounts payable and accrued expenses			(12,495)
Other accrued acquisition costs	256	535	(1,054)
Long-term debt			(17,359)
Cash paid for purchase of IVC Industries, Inc., net of cash acquired	(256)	(535)	(7,112)
Fair value of assumed and issued fully-vested stock options	$	$	$ 1,299
During 2004 and 2003, we acquired other businesses and intellectual property			
Accounts receivable	$ 471	$ 116	$
Inventories	914		
Property, plant and equipment	173	616	
Intangible asset	12,904	10,445	
Other assets	183	39	
Accounts payable and accrued expenses	(2,673)	(356)	
Net deferred tax liabilities	(446)	(1,884)	
Cash paid for purchase of other businesses and intellectual property	(8,524)	(4,007)	
Fair value of common stock issued	$ 3,002	$ 4,969	$
Dividends, interest and amortization of beneficial conversion feature related to preferred stock (Notes 11 and 12(b))	$ 749	$ 958	$ 11,948
Conversion of preferred stock to common stock (Note 12(b))	$ 6,934	$ 3,824	$ 67,881
Conversion of subordinated notes to common stock (Note 6(d))	$ 6,034	$	$

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

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(1) Description of Business and Basis of Presentation

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

Our business is organized into three primary operating segments: (i) consumer diagnostic products, (ii) vitamins and nutritional supplements, and (iii) professional diagnostic products. The consumer diagnostic products segment includes our over-the-counter pregnancy and fertility/ovulation tests. The vitamins and nutritional supplements segment includes branded and private label vitamins and nutritional supplements that are sold over-the-counter. 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 infectious diseases, drugs of abuse and pregnancy.

Our company was incorporated on May 11, 2001 as a wholly-owned subsidiary of Inverness Medical Technology, Inc. ("IMT"). 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 IMT in a merger transaction and, simultaneously, our 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 its non-diabetes businesses (women's health, nutritional supplements and professional diagnostics) were held by our company and our subsidiaries. At the closing of the transaction, all of the shares of our common stock held by IMT were split-off from IMT.

Since the consummation of the split-off and merger described above, we have completed a number of acquisitions. During 2004, we acquired Advantage Diagnostics Corporation ("ADC") on June 16, 2004 and Viva Diagnostika ("Viva") on June 2, 2004 (Note 4(a)). ADC was a closely held lateral flow diagnostic company that specializes in rapid test development and component manufacturing. Viva was a closely held distributor of professional diagnostic products to the German marketplace.

During 2003, we acquired the rapid diagnostics business 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 business 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, we 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 our 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 Unilver Plc (the "Unipath business") on December 20, 2001. 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 consolidated financial statements include the accounts of the entities contributed to us by IMT and the subsequently acquired entities and businesses since their respective acquisition dates, along with the assets, liabilities, revenues and expenses of the businesses. All intercompany accounts and transactions have been eliminated. Our equity accounts for all periods presented reflect the par value of our stock at the date of incorporation, adjusted for the fixed exchange ratio set forth in the Merger Agreement and related agreements and the related stock split; the historical equity accounts of the legal entities that comprise our 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.

(2) Summary of Significant Accounting Policies

(a) Use of Estimates

To prepare our financial statements in conformity with accounting principles generally accepted in the United States of America, our 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

We follow the provisions of Statement of Financial Accounting Standards ("SFAS") No. 52, *Foreign Currency Translation*. In general, the functional currencies of our foreign subsidiaries are the local currencies. For purpose of consolidating the financial statements of our 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 our foreign subsidiaries are translated using the average rates of exchange during each reporting period. Net realized and unrealized foreign currency exchange transaction loss of $0.7 million, gain of $5,000 and loss of $1.6 million during 2004, 2003 and 2002, respectively, are included as a component of other income, net, in the accompanying consolidated statements of operations.

(c) Cash and Cash Equivalents

We consider 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, 2004 and 2003.

(d) Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market and made up of raw material, work in process and finished goods. The costs elements of work in process and finished goods inventory consist of raw material, direct labor and manufacturing overhead. Where finished goods inventory are purchased from third-party manufacturers, the costs of such finished goods inventory represent the costs to acquire such inventory.

(e) Property, Plant and Equipment

We record 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 (3-10 years), buildings (20-39 years), leasehold improvements (lesser of remaining term of lease or estimated useful life of asset), computer software and equipment (3-5 years) and furniture and fixtures (3-10 years). Land is not depreciated. Depreciation and amortization expense related to property, plant and equipment amounted to $13.1 million, $10.1 million and $6.4 million in 2004, 2003 and 2002, respectively. Expenditures for repairs and maintenance are expensed as incurred.

(f) Goodwill and Other Intangible Assets

The following is a summary of goodwill and other intangible assets as of December 31, 2004:

	Gross Carrying Amount	Accumulated Amortization	Useful Life
	(in thousands)		
Amortized intangible assets:			
Core technology and patents	$ 50,347	$ 10,020	1-18 years
Other intangible assets			
Supplier relationships	11,020	2,512	10 years
Trademarks and trade name	9,978	5,133	5-25 years
License agreements	9,747	3,912	7-8.5 years
Customer related intangible assets	9,191	4,277	1.5-15 years
Manufacturing know how	3,500	311	15 years
Other	530	141	2-3 years
	$ 94,313	$ 26,306	
Intangible assets with indefinite lives:			
Goodwill	$ 221,155		
Other intangible assets	50,542		
	$ 271,697		

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

	Gross Carrying Amount	Accumulated Amortization	Useful Life
	(in thousands)		
Amortized intangible assets:			
Core technology and patents	$ 44,458	$ 6,516	1-18 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
Customer related intangible assets	8,831	880	1.5-15 years
Manufacturing know how	3,500	78	15 years
	$ 86,690	$ 16,069	
Intangible assets with indefinite lives:			
Goodwill	$ 216,733		
Other intangible assets	46,719		
	$ 263,452		

We amortize intangible assets with finite lives using primarily the straight-line method over the above estimated useful lives of the respective intangible asset. We believe that that the straight-line method is appropriate in most circumstances, as it approximates the pattern in which economic benefits are consumed. Amortization expense of intangible assets, which in the aggregate amounted to $10.4 million, $6.3 million and $3.9 million in 2004, 2003 and 2002, respectively, is included in cost of sales, research and development and sales and marketing in the accompanying consolidated statements of operations. The allocation of amortization expense to the expense categories is based on the intended usage and the expected benefits of the intangible assets in relation to the expense categories. 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, 2004:

	(in thousands)
2005	$ 8,623
2006	7,709
2007	7,564
2008	7,288
2009	5,635

On January 1, 2002, we adopted SFAS No. 142, *Goodwill and Other Intangible Asset,* and accordingly, no longer amortize 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, we perform annual impairment tests of the carrying value of our goodwill by reporting unit. During 2002, we recorded a goodwill impairment charge of $12.1 million as a result of an appraisal of our nutritional supplement segment (Note 5). Our annual impairment review on September 30, 2004, did not indicate that goodwill

related to our consumer diagnostic products, vitamins and nutritional supplements 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(b) and (e)) and trademarks that were acquired as part of the Unipath business acquisition, have been assigned indefinite lives and therefore, in accordance with SFAS No. 142 are not being amortized.

We allocate goodwill by segment based on the relative percentage of estimated future revenues generated for the respective segment as of the acquisition date. Goodwill amounts allocated to our consumer diagnostic products and professional diagnostic products business segments are summarized as follows:

	Consumer Diagnostic Products	Professional Diagnostic Products	Total
		(in thousands)	
Goodwill, at December 31, 2002	$ 66,493	$ 42,422	$ 108,915
Acquisitions (Note 4)	20,772	86,527	107,299
Other	(589)	1,108	519
Goodwill, at December 31, 2003 (restated)	86,676	130,057	216,733
Acquisitions (Note 4)		4,858	4,858
Other	(598)	162	(436)
Goodwill, at December 31, 2004	$ 86,078	$ 135,077	$ 221,155

We generally expense costs incurred to internally develop intangible assets, except for costs that are incurred to establish patents and trademarks, such as legal fees for initiating, filing and obtaining the patents and trademarks. Amounts capitalized in connection with establishing patents and trademarks are included in other intangible assets, net, in the accompanying consolidated balance sheets. Upon the successful registration of the patents and trademarks, we commence amortization of such intangible assets over their estimated useful lives. Costs incurred to maintain the patents and trademarks are expensed as incurred.

(g) Impairment of Other Long-Lived Tangible and Intangible Assets

On January 1, 2002, we 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. We examine on a periodic basis the carrying value of our 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, we recorded an impairment charge of $12.7 million during 2002, related to trademarks and brand names of our nutritional supplements business (Note 5). We believe that the remaining carrying values of our other long-lived tangible and intangible assets were realizable as of December 31, 2004.

(h) Income Taxes

We follow the provisions of SFAS No. 109, *Accounting for Income Taxes,* under which deferred tax assets and liabilities are determined based on differences between financial reporting and tax bases of assets and liabilities. Deferred tax assets and liabilities are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. 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 we will realize such benefits, we must establish a valuation allowance against the related deferred tax assets (Note 14).

(i) Revenue Recognition

The majority of our revenues are derived from product sales. We 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. We recognize revenue upon title transfer of the products to third-party customers, less a reserve for estimated product returns and allowances. In connection with the acquisition of the Abbott business in September 2003 (Note 4 (b)), we entered into a transition services agreement with Abbott, whereby Abbott would continue to distribute the acquired products sold under the TestPack brand for a period of up to 18 months. During the transition period, we recognize revenue on sales of the TestPack products when title transfers from Abbott to third-party customers.

To a lesser extent, we also receive license and royalty revenue from agreements with third-party licensees. Revenue from fixed fee license and royalty agreements are recognized on a straight-line basis over the obligation period of the related license agreements. License and royalty fees that are calculated based on the licensees' sales are 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.

(j) Employee Stock-Based Compensation Arrangements

We adopted an employee stock option plan in 2001 (Note 12(c)). For all periods presented in the accompanying consolidated financial statements, we accounted for our employee stock-based compensation arrangements using the intrinsic value method under the provisions of Accounting Principles Board ("APB") Opinion No. 25, *Accounting for Stock Issued to Employees*, and related interpretations. We have elected to use the disclosure-only provisions of SFAS No. 123, *Accounting for Stock-Based Compensation*, as amended by SFAS No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure.*

Had compensation expense for stock option grants to employees been determined based on the fair value method at the grant date for awards under the stock option plans consistent with the method

prescribed by SFAS No. 123, our net (loss) income would have been (increased) decreased to the pro forma amounts indicated as follows:

	2004	2003	2002
		(restated)	(restated)
	(in thousands, except per share amounts)		
Net (loss) income as reported	$ (14,238)	$ 9,560	$ (34,783)
Stock-based employee compensation as reported (a)		397	10,268
Pro forma stock-based employee compensation	(5,675)	(6,161)	(18,920)
Net (loss) income pro forma	$ (19,913)	$ 3,796	$ (43,435)
(Loss) income per common share basic			
Net (loss) income as reported	$ (0.75)	$ 0.55	$ (4.70)
Stock-based employee compensation as reported		0.02	1.03
Pro forma stock-based employee compensation	(0.28)	(0.39)	(1.90)
Net (loss) income per share pro forma	$ (1.03)	$ 0.18	$ (5.57)
(Loss) income per common share diluted			
Net (loss) income as reported	$ (0.75)	$ 0.49	$ (4.70)
Stock-based employee compensation as reported		0.02	1.03
Pro forma stock-based employee compensation	(0.28)	(0.35)	(1.90)
Net (loss) income per share pro forma	$ (1.03)	$ 0.16	$ (5.57)

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

We have computed the pro forma disclosures for stock options granted to employees after January 1, 1995 using the Black-Scholes option pricing model prescribed by SFAS No. 123. The assumptions used during each of the three years ended December 31, 2004 were as follows:

	2004	2003	2002
Risk-free interest rate	2.80-3.95%	2.33-3.49%	2.6-4.9%
Expected dividend yield			
Expected lives	5 years	5 years	5 years
Expected volatility	47%	55%	58%

The weighted average fair value under the Black-Scholes option pricing model of options granted to employees during 2004, 2003 and 2002 was $9.86, $9.34 and $9.19, respectively. All options granted during these periods were granted at fair market value on date of grants.

We are required to adopt SFAS No. 123 (revised 2004), *Share-Based Payment* ("SFAS No. 123R") for the interim period beginning after June 15, 2005. Based on the current outstanding unvested number of stock options, we expect to record a compensation charge of $2.7 million in the second half of 2005.

(k) Net (Loss) Income per Common Share

Net (loss) income per common share, computed in accordance with SFAS No. 128, *Earnings per Share*, is based upon the weighted average number of outstanding common shares and the dilutive effect of common share equivalents, such as options and warrants to purchase common stock, convertible preferred stock and convertible notes, if applicable, that are outstanding each year (Note 11).

(l) Other Operating Expenses

We expense advertising costs as incurred. In 2004, 2003 and 2002, advertising costs amounted to $19.9 million, $18.6 million and $14.3 million, 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 we charge our customers for shipping and handling costs, these costs are recorded as product revenues.

(m) Concentration of Credit Risk, Off-Balance Sheet Risks and Other Risks and Uncertainties

Financial instruments that potentially subject us to concentration of credit risk primarily consist of cash and cash equivalents and accounts receivable. We invest our excess cash primarily in high quality securities and limit the amount of our credit exposure to any one financial institution. We do not require collateral or other securities to support customer receivables; however, we perform ongoing credit evaluations of our customers and maintain allowances for potential credit losses.

There were no individual customer accounts receivable balances outstanding at December 31, 2004 and 2003 that were in excess of 10% of the gross accounts receivable balance on those dates. During 2004 and 2003, we had one customer that represented 11% of our net revenues in both years who purchases both our consumer diagnostic products and vitamins and nutritional supplements. There were no customers during 2002 that represented more than 10% of our net revenues.

We rely on a number of third parties to manufacture certain of our products. If any of our third party manufacturers cannot or will not manufacture our products in the required volumes, on a cost-effective basis, in a timely manner, or at all, we will have to secure additional manufacturing capacity. Any interruption or delay in manufacturing could have a material adverse effect on our business and operating results.

In February 2002, we entered into an interest rate swap agreement which was intended to protect us from interest rate fluctuations related to a portion of our senior long-term debt. Other than this interest rate swap agreement, which expired on December 30, 2004, we had no significant off-balance-sheet arrangements or other concentration of credit risks such as foreign exchange contracts, option contracts or other foreign hedging arrangements at December 31, 2004 and 2003. See Note 15 for financial information by geographic area and business segment.

(n) Financial Instruments and Fair Value of Financial Instruments

Our primary financial instruments at December 31, 2004 and 2003 consisted of cash equivalents, accounts receivable, accounts payable and debt. The estimated fair value of these financial instruments approximates their carrying values at December 31, 2004 and 2003. The estimated fair values have been determined through information obtained from market sources. Additionally, our 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, 2004 and 2003, we had no foreign currency exchange forward contracts outstanding. We account for our 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 2004, the Financial Accounting Standards Board ("FASB") issued SFAS No. 151, *Inventory Costs, An Amendment of ARB No. 43, Chapter 4*. SFAS No. 151 clarifies that abnormal amounts of idle facility expense, freight, handling costs and wasted materials should be recognized as current period charges in all circumstances. We are required to adopt SFAS No. 151 on January 1, 2006. We do not expect the adoption of SFAS No. 151 to have a material impact on our consolidated financial statements.

In December 2004, the FASB issued SFAS No. 123R which addresses the accounting for transactions in which a company receives employee services in exchange for (a) equity instruments of the company or (b) liabilities that are based on the fair value of the company's equity instruments or that may be settled by the issuance of such equity instruments. It eliminates the ability to account for share-based compensation transactions using APB Opinion No. 25 and generally requires that such transactions be accounted for using a fair-value-based method. As permitted by the current SFAS No. 123, *Accounting for Stock-Based* Compensation, we have been accounting for share-based compensation to employees using APB Opinion No. 25's intrinsic value method and, as such, we generally recognize no compensation cost for employee stock options. We are required to adopt SFAS No. 123R for the interim period beginning after June 15, 2005. Based on the current outstanding

unvested number of stock options, we expect to record a compensation charge of $2.7 million in the second half of 2005. The adoption of this statement will have no impact on our cash flows.

In December 2004, the FASB issued FASB Staff Position ("FSP") No. 109-1, *Application of FASB Statement No. 109, "Accounting for Income Taxes," to the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004*. FSP No. 109-1 states that the impact of the tax deduction on qualified production activities provided by the American Jobs Creation Act of 2004 (the "Act") should be accounted for as a special deduction rather than a rate reduction. FSP No. 109-1 was effective immediately and had no impact on our 2004 consolidated financial statements.

In December 2004, the FASB issued FSP No. 109-2, *Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004*. FSP No. 109-2 grants a waiver to the SFAS No. 109 requirement to account for the impacts of new legislation in the period of enactment. FSP No. 109-2 was effective immediately and had no impact on our 2004 consolidated financial statements.

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

(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

We restated our originally 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 originally been reported in other income, 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 originally 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 originally been corrected in the periods in which they had been identified rather than in the periods to which they related because they were immaterial to the financial statements for such periods. The restatements related to the foreign exchange gain and sales cut-off and sales incentive allowances were reported in our consolidated financial statements included in our 2003 Annual Report on Form 10-K, Amendment No. 1, filed with the Securities and Exchange Commission ("SEC") on April 22, 2004 and are reflected in the amounts below as "as restated on April 19, 2004."

We further restated our previously issued consolidated financial statements as of and for the years ended December 31, 2003 and 2002 to correct an error in the calculation of the provisions for income taxes and the related deferred tax accounts. We should have reported gross, certain deferred tax liabilities associated with temporary differences related to differing tax and book bases of goodwill and other intangible assets. As a result, we have recorded an additional valuation allowance against the deferred tax assets associated with certain net operating loss carry forwards. The correction of this error resulted in incremental non-cash provisions of income taxes in the amount of $1.9 million and $0.8 million in 2003 and 2002, respectively. In addition, we revised our purchase price allocation in connection with our acquisition of the Abbott business on September 30, 2003 to attribute $5.7 million to customer related intangible assets acquired in the acquisition. We have also recorded and commenced to amortize as of the date of the acquisition $11.3 million of other assets acquired from Abbott, the amortization of a portion of which amounted to approximately $51,000 per quarter. We had originally recognized this amortization beginning in our Quarterly Report on Form 10-Q for the period ended September 30, 2004. Goodwill generated in connection with the acquisition of the Abbott business is reduced by these amounts (Note 4(b)). The impact of this revision of the purchase price allocation is to increase amortization expense by $0.9 million in 2003. The restatements as a result of the error in the calculation of the provision for income taxes and related deferred tax accounts and the revision of the purchase price allocation in connection with the acquisition of the Abbott business and the resultant incremental amortization were reported in our consolidated financial statements included in our 2003 Annual Report on Form 10-K, Amendment No. 3, filed with the SEC on February 11, 2005 and are reflected in the amounts below as "as restated on February 10, 2005."

The following lists the accounts in the consolidated financial statements that were affected by the aforementioned restatements, with comparisons of the restated amounts to the originally reported amounts and the effect of such restatements on income (loss) before cumulative effect of a change in accounting principle, net income (loss) and income (loss) per share. All applicable amounts relating to

the aforementioned restatements have been reflected in these consolidated financial statements and notes hereto.

	2003		
	As restated on February 10, 2005	As restated on April 19, 2004	As originally reported
	(in thousands, except per share amounts)		
Net product sales	*	$ 286,984	$ 286,689
Cost of sales	$ 168,171	*	168,120
Sales and marketing	52,504	*	51,705
Provision for income taxes	3,028	*	1,169
Income before cumulative effect of change in accounting principle	9,560	12,269	11,974
Net income	9,560	12,269	11,974
Income per common share basic:			
Income before cumulative effect of change in accounting principle	$ 0.55	$ 0.72	$ 0.70
Net income	$ 0.55	$ 0.72	$ 0.70
Income per common share diluted:			
Income before cumulative effect of change in accounting principle	$ 0.49	$ 0.64	$ 0.63
Net income	$ 0.49	$ 0.64	$ 0.63

* This amount or balance had not been restated on that date.

	December 31, 2003		
	As restated on February 10, 2005	As restated on April 19, 2004	As originally reported
	(in thousands)		
Inventories	$ 47,423	*	$ 47,043
Property, plant and equipment, net	57,773	*	56,999
Goodwill	216,733	*	233,792
Other intangible assets with indefinite lives	46,719	*	38,119
Core technology and patents, net	37,942	*	36,423
Other intangible assets, net	32,679	*	27,743
Deferred tax assets, non-current	1,456	*	4,075
Accumulated deficit	(72,765)	$ (69,296)	(66,703)
Accumulated other comprehensive income	*	11,813	9,220

* This amount or balance had not been restated on that date.

	2002		
	As restated on February 10, 2005	As restated on April 19, 2004	As originally reported
	(in thousands, except per share amounts)		
Net product sales	*	$ 200,399	$ 201,641
Cost of sales	*	114,653	115,600
Other income, net	*	9,114	11,707
Provision for income taxes	$ 3,443	*	2,683
Loss before cumulative effect of change in accounting principle	(22,635)	(21,875)	(18,987)
Net loss	(34,783)	(34,023)	(31,135)
Loss per common share basic:			
Loss before cumulative effect of change in accounting principle	$ (3.48)	$ (3.40)	$ (3.11)
Net loss	$ (4.70)	$ (4.62)	$ (4.33)
Loss per common share diluted:			
Loss before cumulative effect of change in accounting principle	$ (3.48)	$ (3.40)	$ (3.11)
Net loss	$ (4.70)	$ (4.62)	$ (4.33)

*
This amount or balance had not been restated on that date.

(3) Other Balance Sheet Information

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

	December 31,	
	2004	2003
		(restated)
	(in thousands)	
Inventories:		
Raw materials	$ 23,434	$ 19,986
Work-in-process	14,956	12,631
Finished goods	21,753	14,806
	$ 60,143	$ 47,423
Property, plant and equipment:		
Machinery, laboratory equipment and tooling	$ 67,650	$ 52,202
Land and buildings	9,053	8,919
Leasehold improvements	12,037	8,349
Computer software and equipment	7,358	5,505
Furniture and fixtures	2,992	2,714
	99,090	77,689
Less Accumulated depreciation and amortization	32,310	19,916
	$ 66,780	$ 57,773
Accrued expenses and other current liabilities:		
Compensation and compensation-related	$ 11,121	$ 10,259
Advertising and marketing	9,036	9,146
Professional fees	5,615	6,518
Interest payable	5,631	956
Royalty obligations	5,342	4,810
Other	15,141	9,433
	$ 51,886	$ 41,122

(4) Business Combinations

All of the acquisitions discussed below, with the exception of the IMN acquisition (Note 4 (f)), resulted in the recognition of goodwill. Acquisitions are an important part of our growth strategy. When we acquire businesses, we seek to complement existing products and services, enhance or expand our product lines and /or expand our customer base. We determine what we are willing to pay for each acquisition partially based on our expectation that we can cost effectively integrate the products and services of the acquired companies into our existing infrastructure. In addition, we utilize existing infrastructure of the acquired companies to cost effectively introduce our products to new geographic areas. All these factors contributed to the acquisition prices of the acquired businesses discussed below, that were in excess of the fair value of net assets acquired and the resultant goodwill.

(a) Various Acquisitions

On December 10, 2004, our subsidiary, Inverness Medical Switzerland GmbH ("IMS"), settled a patent infringement lawsuit in Germany against Biomar Diagnostic Systems GmbH ("Biomar") and its principal stockholder. We had alleged that Biomar's rapid diagnostic tests infringed on several of our patents. In advance of a court decision, we and Biomar agreed to settle the litigation under the terms of an agreement through which Biomar agreed to transfer its rapid diagnostic business to us, including the use of the Biomar tradename, in exchange for a release of all past infringement claims. We accounted for this settlement in accordance with Emerging Issues Task Force ("EITF") Issue No. 04-01, *Accounting for Preexisting Relationships between the Parties to a Business Combination*, and recorded the fair values of the assets acquired, aggregating $0.5 million, as a gain in other income, net, in the accompanying statement of operations of 2004.

On June 16, 2004, we acquired ADC, a closely held lateral flow diagnostic company that specializes in rapid test development and component manufacturing. The purchase price of ADC consisted of $2.4 million in cash and $0.2 million in assumed debt. The terms of the merger agreement also provide for $1.5 million of contingent consideration payable to the ADC shareholders upon the successful completion of a new product under development by December 31, 2005. The payment of the contingent consideration, if any, will be recorded as an addition to the purchase price. We believe that the acquisition of ADC and the addition of ADC's chief scientist to our existing staff will deepen our scientific research management and expand our intellectual property capabilities.

On June 2, 2004, we acquired Viva, a closely held distributor of professional diagnostic products to the German marketplace. The purchase price of Viva consisted of $2.6 million in cash, 0.2 million shares of our common stock with an aggregate fair value of $3.0 million and $0.3 million in assumed debt. We believe that Viva, with its established German distribution network, will provide us with expanded distribution channel for our professional diagnostic products, as well as for our cardiac products in development.

The financial results of both ADC and Viva are included in our professional diagnostic products reporting unit.

On November 18, 2003, we acquired SMB, a developer and manufacturer of customized and standard devices for analysis of bio-molecules. The purchase price of SMB consisted of $3.0 million in cash, 0.1 million shares of our common stock with an aggregate fair value of $2.5 million and $0.1 million in assumed debt. Simultaneously with the acquisition, we acquired a technology license from SMB's former parent for $0.2 million. The acquisition of SMB provided us with access to SMB's intellectual property and research and development capabilities. The financial results of SMB are included in our cardiology reporting unit which is included in our Corporate and Other category for purpose of segment reporting (Note 15).

(b) Acquisition of the Abbott business

On September 30, 2003, we 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 complements

our 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 $95.1 million, which consisted of $55.0 million in cash, $37.5 million in the form of 1.6 million shares of our common stock and direct acquisition costs of $2.6 million. We financed the cash portion of the purchase price by obtaining loans under our amended senior credit facility (Note 6(a)).

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

		(in thousands)
Inventories	$	380
Property, plant and equipment		1,310
Goodwill		69,487
Trade name Signify		6,400
Trade name Fact plus		1,600
Trade name TestPack		8,600
Patents		1,570
Customer related intangible assets		5,735
	$	95,082

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 our consolidated statements of operations after the acquisition date as part of each of our 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: $18.8 million to consumer diagnostic products and $50.7 million to professional diagnostic products. We believe the Signify and TestPack trade names represent indefinite-lived intangible assets and estimate the useful life for the Fact plus trade name to be 5 years. The Signify and TestPack trade names and Fact plus trade name are included on the accompanying consolidated balance sheets in trademark and trade names with indefinite lives and other intangible assets, net, respectively. Patents, which values are included in core technology and patents, net, on the accompanying consolidated balance sheets are assigned useful lives ranging from 1 to 18 years. Customer related intangible assets, which values are included in other intangible assets, net, on the accompanying consolidated balance sheets are assigned useful lives ranging from 1.5 to 5 years. The weighted average amortization period for the acquired intangible assets with finite lives is approximately 5 years.

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.

This acquisition resulted in a significant amount of goodwill. Goodwill represents the premium paid in excess of the value we allocated to identifiable assets. Goodwill arose as a result of acquired going concern value, access to employees via the acquisition agreements and synergies. Because of the unique way in which the acquisition of the Abbott business was structured, access to the factors required for maintaining the continuity of the business was achieved through contractual arrangements

with terms of up to two years to facilitate the rapid integration of the Abbott business into our infrastructure with minimal restructuring or exit costs required. For this reason, the vast majority of the goodwill associated with the acquisition was attributable to synergies arising from the application of our existing infrastructure to the acknowledged brands of the acquired business. The acquisition was also attractive because of the similarity in mode of operation between the Abbott products and our existing products.

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

Significant strategic benefits exist in the product breadth that we can now offer to the international professional market through the combined strength of our TestPack and Clearview product lines. This product breadth will allow us to develop a strong and more cost efficient world-wide distribution network for our professional products which we can later leverage to support anticipated new product introductions. Strong brand equity present in the Abbott business also adds significantly to our position as a leading provider of rapid point of care diagnostic tests on a world-wide basis.

(c) Acquisition of ABI

On August 27, 2003, we 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, we 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 our professional diagnostic product portfolio. ABI also provides us with additional manufacturing capabilities and new distribution channels for our professional diagnostic products.

The aggregate purchase price of ABI was $28.8 million, which consisted of $13.4 million in cash, 0.7 million shares of our common stock with an aggregate fair value of $14.3 million and direct acquisition costs of $1.2 million. The fair value of our common stock was determined based on the average market price of our 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.* We financed the cash portion of the purchase price by obtaining a loan under our amended senior credit facility (Note 6(a)).

The following table summarizes the fair value of the assets acquired and liabilities assumed at the date of acquisition:

	(in thousands)
Cash and cash equivalents	$ 1
Accounts receivable	6,368
Inventories	6,056
Property, plant and equipment	4,301
Goodwill	11,258
Customer related intangible asset	2,000
Manufacturing know how	3,500
Other assets	117
Accounts payable and accrued expenses	(4,761)
	$ 28,840

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 our consumer diagnostic products and professional diagnostic products reporting units. We have allocated goodwill of $2.2 million and $9.1 million to the consumer diagnostic 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. We estimate the useful lives of both intangible assets to be 15 years and have included them in other intangible assets, net, in the accompanying consolidated balance sheets. The weighted average amortization period for the acquired intangible assets with finite lives is 15 years.

(d) Acquisition of Ostex

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

The aggregate purchase price of Ostex was $33.7 million, which consisted of 1.6 million shares of our 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 0.3 million shares of our common stock, which options and warrants have an aggregate fair value of $1.8 million, estimated exit costs of $3.9 million, which primarily consists of severance and costs to vacate Ostex's manufacturing and administrative facilities (Note 18(b)) in accordance with EITF Issue No. 95-3, *Recognition of Liabilities in Connection with a Purchase Business Combination,* direct acquisition costs of $1.6 million and $2.9 million in assumed debt. The fair value of our common stock issued to acquire all of Ostex's outstanding common stock was determined based on the average market price of our 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.

The following table summarizes the fair value of the assets acquired and liabilities assumed at the date of acquisition:

	(in thousands)
Cash and cash equivalents	$ 1,271
Accounts receivable	1,289
Inventories	467
Property, plant and equipment	604
Goodwill	25,192
Core technology	5,532
Customer related intangible asset	1,096
Other assets	164
Accounts payable and accrued expenses	(1,953)
	$ 33,662

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 our professional diagnostic products reporting unit and business segment. Goodwill generated from this acquisition is not deductible for tax purposes. We estimated the useful lives of both the core technology and customer related intangible asset to be 15 years and included them in core technology and patents, net, and other intangible assets, net, respectively, in the accompanying consolidated balance sheets. The weighted average amortization period for the acquired intangible assets with finite lives is 15 years.

(e) Acquisition of Wampole

On September 20, 2002, we acquired Wampole, a distributor of professional diagnostic and point-of-care medical diagnostic products primarily in the United States (Note 1). This acquisition allows us to expand our business in the point-of-care market in the United States and provides us with certain intellectual property. The aggregate purchase price of Wampole was $72.1 million, which consisted of $70.5 million in cash and $1.6 million in direct acquisition costs. The acquisition was funded by the issuance of $35.0 million in subordinated debt (Notes 6(c) and (d)) and a portion of our 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:

	(in thousands)
Accounts receivable	$ 8,286
Inventories	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 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 our professional diagnostic products reporting unit and business segment. We have 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 10.8 years. The trade name, patents, and supplier relationships are allocated respectively to other intangible assets with indefinite lives, core technology and patents, net, and other intangible assets, net, on the accompanying consolidated balance sheets.

(f) Acquisition of IMN

On March 19, 2002, we 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, we consolidated certain of our vitamin and nutritional supplement manufacturing at IMN and discontinued most of our outsourced manufacturing arrangements. The aggregate purchase price of IMN was $27.3 million, which consisted of $5.6 million in cash representing $2.50 for each outstanding share of IMN's common stock, fully-vested stock options to purchase an aggregate of 0.1 million shares of our common stock, which options had an aggregate fair value of $1.3 million, calculated using the Black-Scholes option pricing model, $1.6 million in costs to exit certain activities of IMN, primarily severance costs of involuntarily terminated employees in accordance with EITF Issue No. 95-3 (Note 18(b)), $17.4 million in assumed debt and $1.4 million in direct acquisition costs. The acquisition was funded by our existing cash. The aggregate purchase price for IMN was allocated to the acquired assets and assumed liabilities as follows:

		(in thousands)
Cash and cash equivalents	$	476
Accounts receivable		4,716
Inventories		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 our vitamins and nutritional supplements business reporting unit and business segment.

(g) Recent and Pending Acquisitions

On January 24, 2005, we completed the acquisition of the consumer pregnancy test business of Advanced Clinical Systems Pty Ltd ("ACS") for $4.6 million. In acquiring ACS, we obtained the rights to the Crystal Clear brand. Crystal Clear is the leading consumer pregnancy test in Australia and has a leading position in New Zealand.

On February 8, 2005, we entered into a definitive merger agreement with Binax, Inc. ("Binax"), whereby we would acquire 100% of Binax's outstanding common stock. Binax is engaged primarily in

the business of developing, manufacturing, marketing and selling rapid diagnostic tests for the detection of infectious diseases, which tests enable pathogen-specific identification that aid doctors in treatment decisions at the point-of-care. The addition of Binax is expected to be a continuation of our strategic efforts focused on expanding our proprietary technology base and product offerings. We expect to benefit from Binax's established reputation in respiratory diagnostics and the potential new product development opportunities. The merger consideration will consist of (i) 1.4 million shares of our common stock, (ii) $8.6 million in cash less the amount by which expenses incurred by Binax in connection with the merger transaction exceed $0.2 million, and (iii) contingent cash consideration of up to $11.0 million to become payable, if at all, upon the commercialization during the five years following the merger of certain products.

On February 16, 2005, we entered into a definitive agreement to acquire Ischemia Technologies, Inc. ("Ischemia"). The purchase price will include approximately $22.4 million of our common stock, subject to adjustment for certain allocated expenses and liabilities, and assumed liabilities. Using patented intellectual property rights, Ischemia has developed and manufactures and markets the only FDA-cleared in vitro diagnostic test specifically targeted on cardiac ischemia, known as Ischemia Modified Albumin, or IMA. With IMA, when used in conjunction with established ECG and troponin tests, emergency physicians can quickly rule out from three to five times more patients whose chest pain symptoms derive from non-cardiac conditions. We expect the acquisition of Ischemia to fit with our strategy of bringing to market unique cardiac markers and delivery platforms that have the capability to substantially change the diagnosis of cardiovascular disease.

(h) Pro Forma Financial Information

The following table presents selected unaudited financial information of our company, including the Abbott business, ABI, Ostex, SMB, ADC and Viva as if the acquisitions of these entities had occurred on January 1, 2003. The pro forma results exclude adjustments for the business acquired from Biomar as it did not materially affect our results of operations. Further, the pro forma results are derived from the historical financial results of the acquired businesses for all periods presented. In particular, the historical financial results of the acquired Abbott business included net sales and expenses of the acquired product lines. Such expenses include direct costs of sales and other expenses, such as direct promotion and advertising, and other marketing expenses attributable to the product lines, and an allocation of indirect selling, general and administrative expenses based on a historical relationship between sales of these product lines and sales of other similar Abbott products. The pro forma adjustments related to the acquired Abbott business include, among others, the following:

(i) an adjustment for the difference between net product sales recorded in the historical results of the Abbott business and the contractually agreed upon amounts pursuant to a distribution agreement entered into as part of the acquisition; and

(ii) an adjustment to costs of sales for the difference between cost of sales recorded in the historical results of the Abbott business and the contractually agreed upon cost of certain products pursuant to a supply agreement entered into as part of the acquisition.

Because certain common Abbott expenses were allocated to the historical financial results of the business that we acquired based on management estimates as if such product lines had been a standalone business and pro forma adjustments were made to historical sales and cost of sales of the Abbott business we acquired based on agreed upon amounts according to the transition services agreements entered into during the acquisition, the pro forma results are not necessarily indicative of

the results that would have been occurred had the acquisition of the Abbott business and the other acquisitions listed above, been consummated on January 1, 2003 or future results.

	2003
	(unaudited and restated) (in thousands)
Pro forma net revenue	$ 356,693
Pro forma net income	6,313
Pro forma net income available to common stockholders basic and diluted (1)	5,355
Pro forma net income per common share (1):	
Basic	$ 0.29
Diluted	$ 0.27

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

(5) Goodwill and Other Intangible Assets

On January 1, 2002, we adopted SFAS No. 142 which addresses changes in the financial accounting and reporting for acquired goodwill and other intangible assets with indefinite lives. Prior to the adoption of SFAS No. 142, goodwill was being amortized over its estimated useful life. Under SFAS No. 142, we no longer amortize goodwill.

SFAS No. 142 also provides specific guidance for determining and measuring impairment of goodwill. Based upon the results of an impairment review, as required by SFAS No. 142, we recorded an impairment charge of $12.1 million on January 1, 2002, representing the remaining goodwill related to our reporting unit that comprises the nutritional supplement lines we acquired in 1997. This amount represented the excess of the carrying value over the fair value of such asset. The fair value was determined using a combination of the income approach and the market approach of valuing a business. The income approach valued the business by discounting projected future cash flows and the market approach valued the security underlying the business by comparing it to those of similar businesses. The most significant facts and circumstances that led to the conclusion of this impairment were (a) future cash flows from these nutritional supplement lines are expected to be reduced, (b) selling, general and administrative expenses relating to these nutritional supplement lines are forecasted to increase as a percentage of sales, and (c) 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 review of the fair value of the reporting unit underlying our nutritional supplements business indicated a goodwill impairment of that reporting unit, as discussed above, we proceeded to also perform an 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 their fair

value. The fair value of the trademarks and brand names were first calculated by discounting the projected cash flows at the cost of capital for our reporting unit that comprises our nutritional supplement lines. The value indicated by this approach was $5.3 million, but the analysis also indicated that the carrying value was not recoverable. Then the trademarks and brand names were valued using the relief from royalty approach which values these intangible assets as if they were licensed from a third party. The value indicated by the net present value of the cash flows was equivalent to an 8.5% royalty on projected product sales in 2002. However, the brands were experiencing declining revenues with forecasts for declining operating margins. Because of these concerns, a lower royalty rate of 5% was used, which indicated a value of $3.2 million. We used the average of the fair values determined by the two approaches, or approximately $4.2 million, as the carrying value of the trademarks and trade names as of January 1, 2002, which resulted in an impairment charge of $12.7 million during the first quarter of 2002. The impairment charge was included in operating expenses in the accompanying statement of operations in 2002. The remaining carrying value of these intangible assets was $3.6 million at December 31, 2004, which is being amortized over the remaining useful life of the intangible asset of 17 years.

(6) Long-term Debt

We had the following long-term debt balances outstanding:

Senior credit facilities	$ 20,053	$ 124,834
8.75% Senior Subordinated notes	150,000	
10% Subordinated notes	20,000	20,000
9% Subordinated notes		9,000
3% Convertible notes		6,000
IMN credit facilities		13,075
IMN bonds payable		1,450
Other	47	478
	190,100	174,837
Less: Unamortized original issue discount	744	944
Less: Current portion	88	14,055
	$ 189,268	$ 159,838

The following describes each of the above listed debt instruments:

(a) Senior Credit Facilities

On November 14, 2002, we and certain of our subsidiaries entered into a senior credit agreement with a group of banks for credit facilities in the aggregate amount of up to $55.0 million, of which $44.1 million 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(g)). During 2003, to finance the cash portions of our acquisitions of ABI and the Abbott business (Notes 4(b) and (c)), we amended the senior credit agreement, whereby the borrowing capacity under the credit facilities was increased to $135.0 million. The amended senior credit facilities of up to $135.0 million in borrowings 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.

On February 10, 2004, all outstanding borrowings and accrued and unpaid interest under the amended senior credit agreement, aggregating $125.0 million, were prepaid with the proceeds from our sale of $150.0 million of 8.75% senior subordinated notes (the "Bonds" or "Bond issuance") (Note 6(b)). We retained the $50.0 million 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 no later than March 31, 2008. We are required to make mandatory prepayments under the senior credit facilities if we met certain cash flow thresholds, issue equity securities or subordinated debt, or sell assets not in the ordinary course of business. As of December 31, 2004, aggregate borrowings amounted to $20.1 million under the revolving lines of credit. The aggregate unused portion of the revolving lines of credit totaled $29.9 million as of December 31, 2004.

We treated the prepayment of the outstanding borrowings under the senior credit facilities, using the proceeds from 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 revolving lines of credit bear interest at either (i) the London Interbank Offered Rate ("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 2.75% to 3.75% or 1.50% to 2.50%, 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, 2004, the interest rate under the revolving lines of credit, including the applicable margin, was 6.15%. We recorded interest expense, including amortization of deferred financing costs, under these senior credit facilities in the aggregate amount of $2.0 million, $4.6 million and $0.5 million in 2004, 2003 and 2002, respectively. On February 10, 2004, in connection with the prepayment of the outstanding balances under the senior credit agreement, we also recorded additional interest expense of $3.6 million relating to the write-off of the remaining related unamortized deferred financing costs of $3.1 million and a financing fee of $0.5 million paid to the banks.

Borrowings under the senior credit facilities are secured by the stock of certain of our U.S. and European subsidiaries, substantially all of our intellectual property rights and the assets of our business in the U.S. and Europe, excluding those assets of Orgenics Ltd., our Israeli subsidiary, Inverness Medical Shanghai Co., Ltd., our subsidiary in China, Inverness Medical Australia Pty. Ltd., our Australian subsidiary and Unipath Scandinavia AB, our Swedish subsidiary, and the stock of Orgenics Ltd. and certain smaller subsidiaries. Under the senior credit agreement, as amended, we 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 us from paying dividends. As of December 31, 2004, we were in compliance with the covenants.

(b) Senior Subordinated Notes, 8.75%, Principal Amount $150.0 million

On February 10, 2004, we completed the sale of $150.0 million of 8.75% 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 (Note 6(a)) and $9.2 million to prepay our outstanding 9% subordinated promissory notes and related prepayment penalties (Note 6(d)). The remaining $11.4 million of proceeds was used 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. In addition, under the related registration rights agreement, we were to cause the registration statement with the SEC with respect to a registered exchange offer to exchange the notes underlying the Bonds for new notes, to be declared effective under the Securities Act of 1933, as amended, within 240 days after the date of the Bonds issuance and consummate the exchange offer within 270 days after the date of the Bonds issuance. As we were unable to register the exchange offer within the number of days specified, interest on the Bonds increased by 0.25% point per year for the first 90-day period immediately following the default and an additional 0.25% point per year with respect to each subsequent 90-day period up to a maximum amount of additional interest of 1% point. Consequently, as of December 31, 2004, the interest rate at which we accrue interest on the Bonds was 9%. For the period from January 7, 2005 through the middle of March 2005, we are accruing interest at 9.5%. We recorded interest expenses related to the Bonds, including amortization of deferred bond issuance costs, in the aggregate amount of $12.4 million in 2004. On February 14, 2005, we caused the registration statement with respect to the exchange offer to be declared effective and we expect to consummate the registered exchange offer by mid March 2005. As of December 31, 2004, total accrued interest related to the Bonds amounted to $5.0 million.

We may redeem the Bonds, in whole or in part, at any time on or after February 15, 2008, at 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 the guarantee of all borrowings under our senior credit facilities. 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. 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. See Note 19 for guarantor financial information.

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.

(c) Subordinated Promissory Notes, 10%, Principal Amount $20.0 million

On September 20, 2002, we sold units ("Units") having an aggregate purchase price of $20.0 million to private investors to help finance the Wampole acquisition (Note 4(e)). Each Unit consisted of (i) a 10% subordinated promissory note (a "10% Subordinated Note") in the principal amount of $50,000 and (ii) a warrant to acquire 0.4 shares of our common stock at an exercise price of $13.54 per share. In the aggregate, we issued fully vested warrants to purchase 0.2 million shares of our 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 we may prepay the 10% Subordinated Notes at any time, subject to certain prepayment penalties. We may, at our option, repay the 10% Subordinated Notes and pay any prepayment penalty, if applicable, in cash or in shares of our common stock valued at 95% of the average closing price of such stock over the ten consecutive trading days immediately preceding the payment date. The 10% Subordinated Notes are expressly subordinated to up to $150.0 million of indebtedness for borrowed money incurred or guaranteed by our company plus any other indebtedness that we incur to finance an acquisition.

We allocated $1.2 million 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 $1.0 million and a warrant to purchase 38,000 shares of our 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 $0.3 million, 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 $2.5 million in both 2004 and 2003 and $0.7 million in 2002.

Among the purchasers of the 10% Subordinated Notes were three directors and officers of our company and an entity controlled by our chief executive officer, who collectively purchased Units that aggregated $1.9 million in principal amount and warrants to purchase an aggregate of 15,000 shares of our common stock.

(d) Subordinated Promissory Notes, 9%, Principal Amount $9 million, and Convertible Subordinated Promissory Notes, 3%, Principal Amount $6 million

On September 20, 2002, also in connection with the financing of the Wampole acquisition (Note 4(e)), we sold subordinated promissory notes in an aggregate principal amount of $9.0 million (the "9% Subordinated Notes") and subordinated convertible promissory notes in an aggregate principal amount of $6.0 million (the "3% Convertible Notes") to private investors. The 9% Subordinated Notes and 3% Convertible Notes bore interest at 9% and 3% per annum, respectively, on the outstanding principal balance. We recorded interest expense, including amortization of deferred financing costs, on these notes of $0.5 million, $1.0 million and $0.3 million in 2004, 2003 and 2002, respectively.

On February 10, 2004, we prepaid the 9% Subordinated Notes with the proceeds from the Bond issuance (Note 6(b)). The total payment made on the prepayment date aggregated $9.3 million, which represented the principal balance outstanding plus accrued and unpaid interest as well as a prepayment penalty of $0.2 million, which equated to 2% of the principal balance repaid. The prepayment penalty along with the remaining unamortized deferred financing cost write-off, aggregating $0.2 million, was charged to interest expense in February 2004.

The 3% subordinated notes were set to mature on September 20, 2008, subject to acceleration in certain circumstances. In addition, the outstanding principal amount and unpaid interest on the 3% convertible notes would 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 was greater than $22.67, which event occurred on December 8, 2004. Consequently, on December 8, 2004, the 3% subordinated notes and accrued and unpaid interest converted into 0.3 million shares of our common stock.

An entity controlled by our chief executive officer purchased 3% Convertible Notes in the aggregate principal amount of $3.0 million.

(e) IMN Credit Facilities

In connection with the acquisition of IMN, we assumed IMN's borrowings under a senior credit agreement ("IMN Credit Agreement"). Pursuant to the IMN Credit Agreement, as amended, IMN could 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. In October 2004, we repaid the then outstanding borrowings under the IMN Credit Agreement of $14.2 million using borrowings under our senior credit facility (Note 6(a)) and terminated the IMN Credit Agreement. Interest expense, including amortization of deferred financing costs, related to borrowings under the IMN Credit Agreement amounted to $0.7 million, $0.8 million and $0.7 million in 2004, 2003 and 2002, respectively. Upon repayment of borrowings under the IMN Credit Agreement, IMN became a U.S. credit party under our senior credit facility (Note 6(a)) and a guarantor under the Bonds (Notes 6(b) and 19).

(f) IMN Bonds Payable

Also in connection with the acquisition of IMN, we assumed IMN's bonds payable ("IMN Bonds"). The bonds were payable in various installments through June 30, 2007 and the bonds payable balance bore interest at 6.90%. Interest expense, including amortization of deferred financing costs,

related to the IMN Bonds amounted to $0.1 million during both 2004 and 2003 and $0.2 million during 2002. In October 2004, we prepaid the outstanding principal balances and any unpaid interest under the IMN Bonds Payable, aggregating $1.6 million, with borrowings from the senior credit facilities (Note 6(a)).

(g) Term Loans and Revolving Line of Credit

On December 20, 2001, our subsidiary, IMS, 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 $65.0 million, as amended. The proceeds of the Former Credit Agreements were used to finance a portion of the cash used to acquire the Unipath business. 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, we issued the bank a warrant to acquire 65,000 shares of our common stock at nominal cost. We had allocated $1.1 million 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 was $2.7 million.

On November 14, 2002, we prepaid the outstanding principal balances and any unpaid interest under the Former Credit Agreements, aggregating $44.1 million, with proceeds from the senior credit facilities obtained on that date (Note 6(a)). We accounted for the prepayment as an early extinguishment of debt. Accordingly, on November 14, 2002, we accelerated the amortization of the remaining unamortized original issue discount and deferred financing costs of $1.0 million and $2.2 million, respectively, which were recorded as a component of interest expense in the accompanying statement of operations of 2002.

(h) Subordinated Bridge Notes

We entered into a note and warrant purchase agreement pursuant to which, on December 20, 2001, we issued subordinated promissory notes ("Subordinated Bridge Notes") having an aggregate principal amount of $20.0 million for the purpose of funding our acquisition of the Unipath business. 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 our Series A Preferred Stock at the option of the holder. Due to such conversion feature of the notes, we recorded a discount on the notes in the form of a beneficial conversion feature of $3.2 million 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, we also issued 10-year warrants to purchase a total of 55,000 shares of our common stock at an exercise price of $18.12 per share. We allocated $0.7 million 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, including amortization of the original issue discount, beneficial conversion feature and deferred financing costs, was $2.9 million.

On March 6, 2002, we prepaid the Subordinated Bridge Notes, which had an aggregate outstanding balance of $20.0 million and related accrued interest of $0.6 million. We 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 $9.6 million related to the gain on early extinguishment of debt as other income, net, and $1.3 million 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 $9.6 million was calculated by first allocating the reacquisition price to the beneficial conversion feature, measured based on our intrinsic value at the date of extinguishment, with the residual amount allocated to the Subordinated Bridge Notes.

An entity controlled by our chief executive officer was a holder of a $10.0 million Subordinated Bridge Note and holds a warrant, issued in connection with such note, to purchase 28,000 shares of our common stock.

(i) Maturities of Long-Term Debt

The following is a summary of the maturities of long-term debt outstanding on December 31, 2004:

		(in thousands)
2005	$	88
2006		12
2007		
2008		40,000
2009		
Thereafter		150,000
		190,100
Less: Unamortized original issue discount		(744)
	$	189,356

(7) Capital Leases

Our 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 our acquisition of IMN. The aggregate monthly minimum payments remaining under this capital lease are $2.1 million as of December 31, 2004. In addition, we have various other capital leases for certain machinery and equipment and computer equipment that expire at various dates through 2009, with remaining aggregate monthly minimum payments of $0.01 million. 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, 2004:

	(in thousands)
2005	$ 607
2006	605
2007	597
2008	353
2009	14
Total future minimum lease payments	2,176
Less: Imputed interest	(308)
Present value of future minimum lease payments	1,868
Less: Current portion	(467)
	$ 1,401

At December 31, 2004, the capitalized amounts of the building, machinery and equipment and computer equipment under the capital leases were as follows:

	(in thousands)
Machinery, laboratory equipment and tooling	$ 78
Buildings	2,186
	2,264
Less: Accumulated amortization	(958)
	$ 1,306

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

Our company and several of our 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, we match such contributions up to a designated level. Total matching contributions related to employee savings plans were $0.4 million, $0.3 million and $0.1 million in 2004, 2003 and 2002, respectively.

(b) UK Pension Plans

Our subsidiary in England, Unipath Ltd. ("Unipath"), 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 were allowed to join the Unipath Pension Scheme starting on December 1, 2002.

As part of the purchase agreement of the Unipath business in December 2001, we 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 contributed $1.9 million 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*, we recorded an unfunded pension liability of $3.7 million as part of the purchase price of the Unipath business (withdrawal obligation). Such unfunded pension liability represented the excess of the benefit obligation, or $20.5 million over the fair value of the plan assets, or $16.8 million, 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 our restructuring plan upon acquisition, the unfunded pension liability initially recorded by us, or $3.7 million, was reduced by the portion of these employees' severance pay-out that represented pension benefits, or $1.1 million, which was reclassified to severance costs for purposes of aggregating the purchase price of the Unipath business. The net remaining unfunded pension liability of $2.6 million is included in the benefit obligation in the tables which follow.

Through November 2004, the Acquired UK Employees could elect, at their option, to transfer contributions and benefits from the Unilever pension plan to the Defined Benefit Plan. As required, we had established the Defined Benefit Plan and believed that the benefits available under this plan were no less favorable to the Acquired UK Employees than Unilever's plan and we maintained these benefits for the period required by the acquisition agreement. Nevertheless, we were engaged in a dispute with Unilever over the equity of benefits under the old and new plans.

During May 2004, we entered into mediation with Unilever to resolve the differences over the relative levels of benefits in Unilever's Plan and the Defined Benefit Plan. The mediation produced a settlement agreement between Unilever and us dated August 17, 2004. This settlement agreement provided that we would match certain benefits available in the Unilever plan to ensure that the plan was viewed as being no less favorable than the Unilever plan for employees considering whether to transition in November of 2004. These changes increased the benefits available to a retiree under the Defined Benefit Plan to: (i) allow for retirees upon retirement to receive unreduced benefits at age 60 rather than age 65; and (ii) calculate the final pension benefit payable to retirees based on the retirees salary at the date on which pension benefits ceased accruing under the Unipath plan (December 2004) plus 1% over inflation for each year of service after December 2004 until retirement.

In November 2004, the final number of employees who elected to transfer into the Defined Benefit Plan from the Unilever plan was determined. Substantially fewer Acquired UK Employees transferred into the Defined Benefit Plan than were previously anticipated to transfer when the unfunded pension liability was initially established in 2001. As a result, an actuarial gain of $1.8 million was recorded and deferred as a component of other comprehensive income in 2004.

Because the Defined Benefit Plan only operated for one month during 2002, changes in benefit obligations and plan assets and net amount recognized in the accompanying consolidated financial statements during 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 2004 and 2003:

	2004	2003
	(in thousands)	
Change in projected benefit obligation		
Benefit obligation at beginning of year	$ 5,003	$ 2,357
Service cost	1,712	1,481
Interest cost	183	62
Plan participants' contributions	577	559
Plan Amendments	4,926	
Actuarial (gain) loss	(1,315)	445
Benefits paid	(128)	(151)
Foreign exchange impact	688	250
Benefit obligation at end of year	$ 11,646	$ 5,003
Change in accumulated benefit obligation		
Benefit obligation at beginning of year	$ 5,003	$ 2,357
Service cost	1,712	1,481
Interest cost	183	62
Plan participants' contributions	577	559
Plan Amendments	1,740	
Actuarial (gain) loss	(1,315)	445
Benefits paid	(128)	(151)
Foreign exchange impact	532	250
Benefit obligation at end of year	$ 8,304	$ 5,003
Change in plan assets		
Fair value of plan assets at beginning of year	$ 1,964	$ 155
Actual return on plan assets	73	37
Employer contribution	2,536	1,364
Plan participants' contributions	577	559
Benefits paid	(128)	(151)
Foreign exchange impact	305	
Fair value of plan assets at end of year	$ 5,327	$ 1,964
Funded status	$ (6,319)	$ (3,039)
Unrecognized net actuarial (gain) loss	(780)	472
Unrecognized prior service cost	6,642	2,436
Net amount recognized	$ (457)	$ (131)

The net amount recognized in the accompanying consolidated balance sheet that relates to the Defined Benefit Plan during 2004 and 2003 consists of:

	2004	2003
	(in thousands)	
Accrued benefit liability	$ (3,085)	$ (3,001)
Accumulated other comprehensive income		434
Intangible asset	2,628	2,436
Net amount recognized	$ (457)	$ (131)

The measurement date used to determine plan assets and benefit obligations for the Defined Benefit Plan was December 31, 2004 and 2003.

The following table provides the weighted-average actuarial assumptions:

	2004	2003
Assumptions used to determine benefit obligations		
Discount rate	5.30%	5.50%
Rate of compensation increase	3.55%	4.25%
Assumptions used to determine net periodic benefit cost in 2003		
Discount rate	5.50%	5.70%
Expected return on plan assets	6.00%	6.20%
Rate of compensation increase	4.25%	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:

	2004	2003
	(in thousands)	
Service cost	$ 1,712	$ 1,481
Interest cost	183	62
Expected return on plan assets	(183)	(64)
Recognition of prior service cost	1,099	
Amortization of net loss	24	
Net periodic benefit cost	$ 2,835	$ 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, 2004, these stocks and fixed income securities represented 71% and 29%, respectively, of the market value of the pension assets. We expect to contribute approximately 0.3 million British Pounds Sterling (or $0.6 million at December 31, 2004) to the Defined Benefit Plan in 2005. We expect benefits to be paid to plan participants of approximately $0.1 million per year for each of the next five years and for benefits totaling $0.8 million to be paid for the five years thereafter.

In 2004 and 2003, Unipath contributed $0.3 million and $0.2 million 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.

(9) Derivative Instrument

We entered into an interest rate swap agreement with one of our lenders, effective February 25, 2002, which was intended to protect our long-term debt on which interest was charged at the LIBOR against fluctuation in such rate. Under the interest rate swap agreement, the LIBOR was 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, we recorded income of $0.7 million and $0.5 million during 2004 and 2003, respectively, and expense of $1.2 million during 2002 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. The interest rate swap agreement expired on December 30, 2004.

(10) Commitments and Contingencies

(a) Operating Leases

We have operating lease commitments for certain of our 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, 2004:

	(in thousands)
2005	$ 6,377
2006	6,131
2007	5,990
2008	4,911
2009	4,316
Thereafter	40,364
	$ 68,089

Rent expense relating to operating leases was approximately $7.4 million, 5.8 million and $4.3 million during 2004, 2003 and 2002, respectively.

The operations of the Unipath business in England are currently housed in a 150,000 square foot manufacturing, research and office facility in Bedford, England. The lease of this facility is between Unilever and a third party landlord and the Unipath business in England continues to use the facility pursuant to an agreement with Unilever in connection with the acquisition. Future minimum annual rent payments under this facility lease range from 1.5 million British Pounds Sterling to 1.6 million British Pounds Sterling (approximately $2.9 million to $3.1 million) 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 us for our remaining term. Because we are required to pay all amounts owed under the lease, as agreed upon at the acquisition, we have included in the table above all future minimum lease payments under this facility lease. If Unilever is unable to successfully assign the lease to us or otherwise enable us to realize the benefit of our 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.

(b) Capital Expenditure Commitments

At December 31, 2004, we had total outstanding non-cancelable equipment purchase commitments of $5.4 million.

(c) Legal Proceedings

Because of the nature of our business, we may be subject at any particular time to customer product claims or various other lawsuits arising in the ordinary course of our 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 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.

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 result in counterclaims challenging the validity of our patents and other rights. In addition, a final ruling on such counterclaims against us could have a material adverse impact on our sales, operations or financial performance.

We previously had several lawsuits pending against Pfizer Inc. and certain other parties, including Princeton BioMeditech ("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. A reasonable estimate of the possible loss or range of loss, if any, cannot be made.

In January 2004, our subsidiary, IMS, filed suit against Quidel Corporation in Germany 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 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. 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 to which we have a license, and that these patents are invalid and/or unenforceable. Quidel seeks injunctive relief and damages. 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. During May 2004, the Court held hearings regarding construction of the patents at issue and rejected various arguments made by Quidel in an effort to limit the scope of certain of our patents. Claim construction hearings regarding the Quidel patent and other remaining patents are ongoing. In September 2004, Quidel served a suit on Unipath Diagnostics GmbH and its directors in the District Court of Mannheim, Germany, alleging infringement of the German equivalent of the Quidel Patent. We have responded, denying liability, and the proceeding is ongoing. We intend to vigorously defend the Quidel claims and vigorously prosecute our infringement counterclaims and separate claims to enforce our intellectual property rights. A reasonable estimate of the possible loss or range of loss, if any, cannot be made.

(d) Recent Settlements of Litigation and Dispute

On February 23, 2005, we settled a dispute of royalty charges with Becton, Dickinson and Company ("BD"), whereby we paid $2.0 million in past royalties to BD. The dispute was a pre-acquisition contingency we assumed as part of the acquisition of ABI (Note 4(c)), for which we had established an estimated contingency reserve of $2.9 million on the date of the acquisition. Consequently, we reversed $0.9 million of the reserve and recorded such income in other income, net, in the accompanying consolidated statement of operations of 2004.

On February 2, 2005, our IMN subsidiary received $8.4 million representing its pro rata share of the net funds which were dispersed in connection with the settlement of class action suits against several raw material suppliers. The class action suits alleged that certain defendants unlawfully agreed to fix prices of certain vitamin products sold in the United States. IMN's recovery represented 7.3% of its approved purchases from the settling parties during the period in which the price fixing was alleged.

(e) Co-development Agreement with ITI Scotland Limited

On February 25, 2005, we entered into a co-development agreement with ITI Scotland Limited ("ITI Scotland"), whereby ITI Scotland agreed to provide us with approximately $57.0 million over three years to partially fund research and development programs focused on identifying novel biomarkers and near-patient and home use tests for cardiovascular and other diseases. We agreed to invest $72.0 million of our planned research and development spending in these programs over the next three years. Through our subsidiary, Stirling Medical Innovations Limited, we intend to establish a new research center in Stirling, Scotland, where we will consolidate many of our existing cardiology programs and ultimately commercialize products arising from these programs.

(f) Joint Venture in China

In September 2004, we began manufacturing a small amount of product in China through a third party. In February 2005, we entered into a joint venture with this Chinese manufacturer and acquired controlling ownership of the manufacturing facility.

(11) (Loss) Income per Share

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

	2004	2003	2002
		(restated)	(restated)
	(in thousands, except per share amounts)		
Numerator:			
(Loss) income before cumulative effect of a change in accounting principle	$ (14,238)	$ 9,560	$ (22,635)
Dividends, redemption interest and amortization of beneficial conversion feature related to Series A Preferred Stock (Note 12(b))	(749)	(958)	(11,948)
(Loss) income before cumulative effect of a change in accounting principle available to common stockholders basic and diluted	(14,987)	8,602	(34,583)
Cumulative effect of a change in accounting principle			(12,148)
Net (loss) income available to common stockholders basic and diluted	$ (14,987)	$ 8,602	$ (46,731)
Denominator:			
Denominator for basic (loss) income per share weighted average shares	19,969	15,711	9,940
Effect of dilutive securities:			
Employee stock options		635	
Warrants		213	
Restricted stock and escrow shares		931	
Potential dilutive common shares		1,779	
Denominator for dilutive (loss) income per share adjusted weighted average shares and assumed conversions	19,969	17,490	9,940
(Loss) income per share basic:			
(Loss) income before cumulative effect of a change in accounting principle	$ (0.75)	$ 0.55	$ (3.48)
Cumulative effect of a change in accounting principle			(1.22)
Net (loss) income	$ (0.75)	$ 0.55	$ (4.70)
(Loss) income per share diluted:			
(Loss) income before cumulative effect of a change in accounting principle	$ (0.75)	$ 0.49	$ (3.48)
Cumulative effect of a change in accounting principle			(1.22)
Net (loss) income	$ (0.75)	$ 0.49	$ (4.70)

We had the following potential dilutive securities outstanding on December 31, 2004: options and warrants to purchase an aggregate of 4.3 million shares of our common stock at a weighted average exercise price of $16.43 per share. Potential dilutive securities were not included in the computation of diluted loss per share in 2004 because the inclusion thereof would be antidilutive.

We had the following potential dilutive securities outstanding on December 31, 2003: (a) options and warrants to purchase an aggregate of 0.8 million shares of our common stock at a weighted average exercise price of $22.87 per share, (b) 3% Convertible Notes convertible into an aggregate of 0.3 million shares of our common stock and (c) Series A Preferred Stock convertible into an aggregate of 0.4 million shares of our 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 related interest and dividends, would be antidilutive.

We had the following potential dilutive securities outstanding on December 31, 2002: (a) options and warrants to purchase an aggregate of 3.5 million shares of our common stock at a weighted average exercise price of $14.65 per share, (b) Series A Preferred Stock convertible into an aggregate of 0.6 million shares of our common stock, (c) 3% Convertible Notes convertible into an aggregate of 0.3 million shares of our common stock, (d) 1.2 million shares of unvested restricted common stock issued to certain executive officers, and (e) 16,000 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.

(12) Stockholders' Equity

(a) Common Stock

As of December 31, 2004, we had 50.0 million shares of common stock, $0.001 par value, authorized, of which 20.7 million shares were issued and outstanding, 3.9 million shares were reserved for issuance upon grant and exercise of stock options under current stock option plans and 0.7 million shares were reserved for issuance upon exercise of outstanding warrants.

(b) Preferred Stock

As of December 31, 2004, we had 5.0 million shares of preferred stock, $0.001 par value, authorized, of which 2.7 million shares were designated as Series A Preferred Stock, $0.001 par value. On March 6, 2002, we sold to private investors 0.5 million shares of Series A Preferred Stock at $39.01 per share for gross proceeds of $20.8 million. On December 20, 2001, we sold to private investors 2.0 million shares of Series A Preferred Stock at $30.00 per share for gross proceeds of $59.9 million. During 2004, 2003 and 2002, 0.2 million, 0.1 million and 2.2 million shares of Series A Preferred Stock, respectively, were converted into 0.4 million, 0.2 million and 4.4 million shares of our common stock, respectively. No shares of Series A Preferred Stock remained outstanding as of December 31, 2004.

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 our common stock was less than $15.00. As a result, we recorded dividends of $33,000 and $0.3 million 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 2004, as our stock price did not close below $15.00 during the period in 2004 in which shares of 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 any of the shares of Series A Preferred Stock.

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 $2.00 (or 11.8%), respectively, to the fair value of our common stock on the respective issuance dates. In accordance with EITF Issue No. 98-5 and EITF Issue No. 00-27, we recorded a beneficial conversion feature in the form of a discount on the two issuances of Series A Preferred Stock of $2.9 million and $8.0 million, 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 2004, 2003 and 2002, we amortized $0.7 million, $0.5 million and $9.6 million, respectively, of such discount, of which $0.7 million,

$0.4 million and $8.8 million, respectively, represented acceleration of amortization due to conversions of Series A Preferred Stock.

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, we had classified the outstanding Series A Preferred Stock outside of stockholders' equity in the accompanying consolidated balance sheet as of December 31, 2003. 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. We recorded accrued redemption interest of $10,000, $0.4 million and $2.0 million in 2004, 2003 and 2002, respectively, which reduced earnings available to common stockholders in the computation of earnings per share (Note 11).

(c) Stock Options and Awards

In 2001, we adopted the 2001 Stock Option and Incentive Plan (the "2001 Plan") which allows for the issuance of up to 5.3 million 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, 2004, there were 0.3 million shares available for future grant under the 2001 plan.

On August 15, 2001, we sold to our chief executive officer 1.2 million shares of restricted common stock at a price of $9.13 per share. Two-thirds of the restricted stock, or 0.8 million shares, vest ratably over 36 months; the remaining one-third, or 0.4 million 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 our 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 $0.5 million for each of the years ended December 31, 2004, 2003 and 2002. We accounted for this arrangement pursuant to FASB Interpretation ("FIN") No. 44, *Accounting for Certain Transactions Involving Stock Compensation*, 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, we measured total compensation expense to be approximately $10.6 million 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, we could repurchase unvested shares at cost in certain circumstances. In February 2002, the terms of the restricted stock agreement were amended, pursuant to which we may repurchase unvested shares at the then fair value in certain circumstances. Also, in connection with this amendment, the chief executive officer surrendered 50,000 shares of his

nonqualified stock options. Because the repurchase rights on unvested shares are at fair value subsequent to the amendment in February 2002, we 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 $10.1 million in 2002, 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 our company prior to the full vesting of this security, additional compensation expense would be recorded.

In August 2001, we granted two nonqualified stock options to purchase an aggregate of 0.8 million 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 $0.2 million for each year ended December 31, 2004, 2003 and 2002, respectively. Shares issued upon exercise vest ratably over 36 months and are fully vested at December 31, 2004.

Upon the split-off and merger in November 2001 (Note 1), each outstanding IMT stock option (the "IMT Options") was exchanged for an option to purchase shares of our common stock 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 option split also required that the ratio of intrinsic value to market value for each option be the same. Consequently, the new exercise prices of our options and the Johnson and Johnson options were determined based on the relative fair values of our common stock and the Johnson & Johnson common stock on the first trading day immediately after the split-off and merger, taking into consideration the relative exchange ratios. Accordingly, the total number of shares of common stock underlying stock options that we issued in the split-off was 0.9 million. Concurrent with the option split, (1) the vesting for all our options was accelerated and (2) the period of exercisability for IMT employees who did not become employees of our company was extended. Such actions are deemed to be award modifications pursuant to FIN No. 44. Under FIN No. 44, we 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 our company, the recognition of this charge was immediate and recorded as stock-based compensation in 2001. For IMT employees who became our employees, we have measured this potential charge, a maximum of $1.2 million, at the date of the modification, but will not record any such compensation charge unless and until such time as these employees terminate their employment with us. 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, we recognized stock-based compensation expense related to certain of the IMT employees who became our employees in the amount of $2,000 and $0.1 million, respectively, as such employees terminated their employment with us. No such stock-based compensation charge was recognized in 2004.

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

	2004		2003		2002	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
	(in thousands, except per share amounts)					
Outstanding at January 1	3,398	$ 15.85	2,754	$ 14.84	1,955	$ 12.77
Granted	394	21.75	1,090	18.71	1,116	17.72
Exercised	(90)	10.40	(271)	11.49	(140)	4.97
Forfeited	(83)	18.12	(175)	24.62	(177)	17.95
Outstanding at December 31	3,619	$ 16.58	3,398	$ 15.85	2,754	$ 14.84
Exercisable at December 31	2,141	$ 15.06	1,591	$ 14.10	1,134	$ 12.25

The following represents additional information related to stock options outstanding and exercisable at December 31, 2004:

	Outstanding			Exercisable	
Exercise Price	Number of Shares	Weighted Average Remaining Contract Life	Weighted Average Exercise Price	Number of Shares	Weighted Average Exercise Price
	(in thousands, except contractual lives and per share amounts)				
$0.75	10	0.79	$ 0.75	10	$ 0.75
1.24-1.80	139	2.49	1.45	139	1.45
1.88-2.44	102	4.37	2.40	102	2.40
2.89-4.32	14	3.19	3.99	14	3.99
4.38-6.48	34	2.70	4.78	34	4.78
6.67-9.60	133	7.47	9.42	72	9.28
10.85-16.20	1,550	7.36	15.23	968	15.13
16.32-24.25	1,574	8.02	20.52	769	19.37
25.40-35.47	51	7.63	27.27	21	27.92
41.05-59.58	7	4.51	44.75	7	44.75
62.42-70.93	3	4.01	65.73	3	65.73
106.39-139.72	1	2.76	117.88	1	117.88
165.96	1	2.91	165.96	1	165.96
	3,619	7.30	$ 16.58	2,141	$ 15.06

(d) Warrants

The following is a summary of all warrant activity during the three years ended December 31, 2004:

	Number of Shares	Exercise Price	Weighted Average Exercise Price
	(in thousands, except per share amounts)		
Warrants outstanding and exercisable, December 31, 2001	621	$ 0.001-21.28	$ 13.09
Granted	238	10.90-13.54	13.10
Exercised	(58)	0.75-7.50	0.94
Forfeited	(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
Forfeited	(1)	15.84	15.84
Warrants outstanding and exercisable, December 31, 2003	712	3.81-23.76	15.62
Exercised	(9)	11.55-14.17	13.03
Forfeited	(4)	9.89-18.25	14.06
Warrants outstanding and exercisable, December 31, 2004	699	$ 3.81-23.76	$ 15.66

The following represents additional information related to warrants outstanding and exercisable at December 31, 2004:

	Outstanding and Exercisable		
Exercise Price	Number of Shares	Weighted Average Remaining Contract Life	Weighted Average Exercise Price
	(in thousands, except contractual lives and per share amounts)		
$3.81-5.57	10	5.54	$ 4.77
7.37-10.90	42	7.77	10.73
13.54-18.12	643	4.15	16.10
23.76	4	0.81	23.76
	699	4.37	$ 15.66

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 0.4 million shares of our common stock were issued to officers and directors of our company or entities controlled by these officers and directors and were outstanding at December 31, 2004. The value of warrants

issued in connection with debt financings have yielded original issue discounts and additional interest expense of $0.2 million for both 2004 and 2003 and $0.5 million in 2002. We believe that our 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, we adopted the 2001 Employee Stock Purchase Plan under which eligible employees are allowed to purchase shares of our 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 our common stock at either the beginning or end of the offering period, whichever is lower. We may issue up to 0.5 million shares of common stock under this plan. At December 31, 2004, 0.2 million shares had been issued under this plan.

(f) Executive Bonus Plan

In 2001, we 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 of our key executives are entitled to receive, on an annual basis, option grants to be awarded at fair value on date of grants if shares of our 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 0.7 million. No performance targets have been achieved as of December 31, 2004.

(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, 2004 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)
		(in thousands)		
Balance at December 31, 2001	$ 1,667	$	$	$ 1,667
Period change	4,817			4,817
Balance at December 31, 2002 (restated)	6,484			6,484
Period change	5,627	(434)	136	5,329
Balance at December 31, 2003(restated)	12,111	(434)	136	11,813
Period change	5,241	434	33	5,708
Balance at December 31, 2004	$ 17,352	$	$ 169	$ 17,521

(i) The balance of $0.2 million 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 sheets.

(ii) All of the components of accumulated other comprehensive income relate to our foreign subsidiaries. No adjustments for income taxes were recorded against other comprehensive income as we intend to permanently invest in our foreign subsidiaries in the foreseeable future.

(14) Income Taxes

Our income tax provision in 2004, 2003 and 2002 mainly represents those recorded by us and certain of our U.S. subsidiaries and by our foreign subsidiaries Unipath Limited in the United Kingdom and Inverness Medical Switzerland GmbH in Switzerland. (Loss) income before income taxes consists of the following:

	2004	2003	2002
		(restated)	(restated)
		(in thousands)	
United States	$ (17,744)	$ 207	$ (24,672)
Foreign	5,781	12,381	5,480
	$ (11,963)	$ 12,588	$ (19,192)

Our primary temporary differences that give rise to the deferred tax asset and liability are net operating loss ("NOL") carryforwards, 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,	
	2004	2003
		(restated)
	(in thousands)	
Deferred tax assets:		
NOL and capital loss carryforwards	$ 45,376	$ 34,107
Tax credit carryforwards	833	833
Nondeductible reserves	8,179	7,020
Nondeductible accruals	10,312	9,132
Difference between book and tax bases of tangible assets	212	595
Difference between book and tax bases of intangible assets	19,004	20,313
Gross deferred tax asset	83,916	72,000
Valuation allowance	(80,225)	(69,366)
Deferred tax asset	3,691	2,634
Deferred tax liabilities:		
Difference between book and tax bases of tangible assets	2,382	6,116
Difference between book and tax bases of intangible assets	10,214	3,002
Deferred tax liability	12,596	9,118
Net deferred tax liability	$ 8,905	6,484

As of December 31, 2004, we had approximately $105.3 million of domestic NOL carryforwards and $25.9 million of foreign NOL and foreign capital loss carryforwards, which either expire on various dates through 2024 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 domestic NOL carryforwards include approximately $48.5 million of pre-acquisition losses at IMN, Ostex and ADC. These pre-acquisition losses are subject to the Internal Revenue Service Code Section 382 limitation. Section 382 imposes an annual limitation on the use of these losses to an amount equal to the value of the company at the time of the ownership change multiplied by the long-term tax exempt rate. The valuation allowance relates to our U.S. NOLs 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 and NOL carryforwards, 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, 2004, $21.6 million of our 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 our income tax expense. Included in the valuation allowance is approximately $1.8 million related to certain NOL 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.

The estimated amount of undistributed earnings of our foreign subsidiaries is $19.6 million at December 31, 2004. No amount for U.S. income tax has been provided on undistributed earnings of our foreign subsidiaries because we consider such earnings to be indefinitely reinvested. In the event of distribution of those earnings in the form of dividends or otherwise, we 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.

In accordance with SFAS No. 109 and SFAS No. 5, *Accounting for Contingencies*, we established reserves for tax contingencies that reflect our best estimate of the transactions and deductions that we may be unable to sustain or that we could be willing to concede as part of a broader tax settlement. We are currently undergoing routine tax examinations by various state and foreign jurisdictions. Tax authorities periodically challenge certain transactions and deductions we reported on our income tax returns. We do not expect the outcome of these examinations, either individually or in the aggregate, to have a material adverse effect on our financial position, results of operations, or cash flows.

On October 22, 2004, the American Jobs Creation Act of 2004 (the "Act") was signed into law. The Act contains a one-time foreign dividend repatriation provision, which provides for a special deduction with respect to certain qualifying dividends from foreign subsidiaries for a limited period. The deduction is subject to a number of limitations and uncertainty remains as to how to interpret numerous provisions in the Act. However, we believe that we have the information necessary to make an informed decision on the impact of the Act on our repatriation plans. We have determined that we will not repatriate any of our foreign earnings under the foreign dividend repatriation provision of the Act.

The Act also provides a deduction for income from qualified domestic production activities, which will be phased in from 2005 through 2010. Under the guidance of FSP No. 109-1, the deduction will be treated as a "special deduction" as described in SFAS No. 109. Therefore, the special deduction has no effect on deferred tax assets and liabilities existing at the enactment date. The impact of this deduction will be reported in the period in which the deduction is claimed on our tax return. We expect that the effect of the phase in of this new deduction will result in no benefit to our effective tax rate until the U.S. NOL carryforwards are fully utilized.

The following table presents the components of our provision for income taxes:

	2004	2003	2002
		(restated)	(restated)
		(in thousands)	
Current			
State	$ 404	$ 419	$ 322
Foreign	(365)	1,465	2,357
	39	1,884	2,679
Deferred			
Federal	2,341	1,687	675
State	209	172	85
Foreign	(314)	(715)	4
	2,236	1,144	764
Total tax provision	$ 2,275	$ 3,028	$ 3,443

The following table presents a reconciliation from the U.S. statutory tax rate to our effective tax rate:

	2004	2003	2002
		(restated)	(restated)
Statutory rate	35%	35%	(34)%
Effect of losses and expenses not benefited	1	1	17
Rate differential on foreign earnings	12	(22)	(15)
Research and development benefit	8	(6)	
State income taxes, net of federal benefit	(3)	3	2
Change in valuation allowance	(72)	13	48
Effective tax rate	(19)%	24%	18%

(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. Our chief operating decision making group is composed of the chief executive officer and members of senior management. Our reportable operating segments are Consumer Diagnostic Products, Vitamins and Nutritional Supplements, Professional Diagnostic Products, and Corporate and Other. Included in the operating results of Corporate and Other are non-allocable corporate expenditure and expenses related to our research and development activities in the area of cardiology, the latter of which amounted to $17.9 million and $11.3 million in 2004 and 2003, respectively, and was nominal in 2002. Expenditure for property, plant and equipment related to our research and development activities in the area of cardiology, which are included in Corporate and Other in the tables below, amounted to $4.4 million in 2004, but were insignificant in 2003 and 2002.

The accounting policies of the segments are the same as those described in the summary of significant accounting policies. We evaluate performance of our operating segments based on revenue and operating income (loss). Revenues are attributed to geographic areas based on where the customer is located. Segment information for 2004, 2003, and 2002 are as follows:

2004	Consumer Diagnostic Products	Vitamins and nutritional supplements	Professional Diagnostic Products	Corporate and Other	Total
			(in thousands)		
Net revenue to external customers	$ 164,211	$ 77,923	$ 134,776	$	$ 376,910
Operating income (loss)	25,543	(1,003)	10,503	(28,299)	6,744
Depreciation and amortization	9,642	3,686	9,430	742	23,500
Restructuring charge	1,725				1,725
Assets	243,001	48,072	269,343	6,762	567,178
Expenditures for property, plant and equipment	6,779	2,530	6,499	4,581	20,389

2003	Consumer Diagnostic Products	Vitamins and nutritional supplements	Professional Diagnostic Products	Corporate and Other	Total
	(restated)	(restated)	(restated)		(restated)
			(in thousands)		
Net revenue to external customers	$ 134,877	$ 71,637	$ 90,198	$	$ 296,712
Operating income (loss)	20,685	3,556	10,416	(18,799)	15,858
Depreciation and amortization	7,349	3,632	5,288	166	16,435
Stock-based compensation	92		12	343	447
Assets	228,175	52,973	253,819	5,032	539,999
Expenditures for property, plant and equipment	5,912	1,496	3,084	643	11,135

2002	Consumer Diagnostic Products	Vitamins and nutritional supplements	Professional Diagnostic Products	Corporate and Other	Total
	(restated)	(restated)	(restated)		(restated)
			(in thousands)		
Net revenue to external customers	$ 114,590	57,909	$ 34,305	$	$ 206,804
Operating income (loss)	10,861	(10,274)	3,691	(17,515)	(13,237)
Depreciation and amortization	5,015	2,755	2,091	447	10,308
Charge related to asset impairment		12,682			12,682
Stock-based compensation				10,625	10,625
Assets	157,912	61,842	107,407	29,334	356,495
Expenditures for property, plant and equipment	4,172	248	1,475	182	6,077

	2004	2003 (restated)	2002 (restated)
		(in thousands)	
Revenue by Geographic Area			
United States	$ 225,559	$ 189,558	$ 110,539
Europe	100,693	71,099	69,373
Other	50,658	36,055	26,892
	$ 376,910	$ 296,712	$ 206,804

	December 31,	
	2004	2003 (restated)
		(in thousands)
Long-lived Tangible Assets by Geographic Area		
United States	$ 29,946	$ 29,232
United Kingdom	27,337	22,981
Ireland	5,897	3,557
Other	3,600	2,003
	$ 66,780	$ 57,773

(16) Transition Services Agreement with IMT

Prior to the split-off from IMT (Note 1), we entered into transition services agreements, whereby we 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 our U.S. subsidiary, Inverness Medical, Inc. ("IMI") and product packaging services provided by our Irish subsidiary, Cambridge Diagnostics Ireland Ltd. ("CDIL") related to certain diabetes businesses and products. Since the split-off from IMT, IMI has charged approximately $0.2 million and $1.9 million during 2003 and 2002, respectively, in transition service fees to IMT, which it believes to approximate arm's-length costs. These fees reduced our general and administrative expenses during the respective periods. Since the split-off from IMT, CDIL generated $5.1 million during 2002 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.

(17) Valuation and Qualifying Accounts

We have 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 our accounts receivable reserve accounts:

	Balance at Beginning of Period	Provision	Amounts Charged Against Reserves	Balance at End of Period
	(in thousands)			
Year ended December 31, 2002 (restated)	$ 2,595	$ 20,470	$ (15,527)	$ 7,538
Year ended December 31, 2003	7,538	19,617	(19,663)	7,492
Year ended December 31, 2004	7,492	27,908	(26,041)	9,359

We have established reserves against obsolete and slow-moving inventories. The activity in the table below includes all inventory reserves. Provisions for obsolete and slow-moving inventories are recorded as a component of costs of sales. The following table sets forth activities in our inventory reserve accounts:

	Balance at Beginning of Period	Provision	Amounts Charged Against Reserves	Balance at End of Period
	(in thousands)			
Year ended December 31, 2002	$ 1,805	$ 483	$ (1,013)	$ 1,275
Year ended December 31, 2003	1,275	1,810	(996)	2,089
Year ended December 31, 2004	2,089	6,761	(4,724)	4,126

(18) Restructuring Activities

In connection with our acquisitions of the Unipath business, IMN and Ostex, we recorded restructuring costs as part of the respective aggregate purchase prices in accordance with EITF Issue No. 95-3 (Note 4). During 2004, we completed a plan of restructuring at our manufacturing operations at Unipath. The following table sets forth the aggregate restructuring costs and balances recorded in connection with the restructuring activities of the acquired businesses and the 2004 restructuring activities at Unipath:

	Balance at Beginning of Period	Costs Included in Purchase Price	Amounts Paid	Other(i)	Balance at End of Period
	(in thousands)				
Year ended December 31, 2002	$ 2,340	$ 3,406	$ (3,592)	$ 118	$ 2,272
Year ended December 31, 2003	2,272	3,632	(2,081)	129	3,952
Year ended December 31, 2004	3,952	2,034	(3,467)	107	2,626

(i) Represents foreign currency translation adjustment.

The following describes our recent restructuring plan and other restructuring plans for which we had remaining obligations as of December 31, 2004.

(a) Recent Restructuring Plan

In the third quarter of 2004, we completed a plan of restructuring at our operations at Unipath, our manufacturing facility in Bedford, England, to reduce operating expenses and organizational complexities and increase overall accountability at Unipath. As a result, we recorded a $1.7 million restructuring charge in the third quarter of 2004, which is included in cost of sales in the accompanying statements of operations, to cover costs for severance, early retirement and outplacement services. The total number of involuntarily terminated employees was 18, all of whom were terminated as of December 31, 2004. As of December 31, 2004, substantially all restructuring costs have been paid.

(b) Restructuring Plans Related to Business Combinations

As a result of the merger with Ostex (Note 4(d)), we established a restructuring plan whereby we exited the facilities of Ostex in Seattle, Washington, and combined the activities of Ostex with our existing manufacturing and distribution facilities. The total number of employees to be terminated involuntarily under the restructuring plan is 38, of which one remained to be terminated as of December 31, 2004. Total severance costs associated with employees to be terminated involuntarily are $1.6 million, of which substantially all has been paid as of December 31, 2004. Costs to vacate the Ostex facilities were $0.5 million, of which $0.2 million were paid as of December 31, 2004. Additionally, the remaining costs to exit operations, primarily facilities lease commitments, are $1.9 million, of which $1.4 million were paid as of December 31, 2004. Total unpaid exit costs amounted to $0.9 million as of December 31, 2004.

Immediately after the close of the acquisition, we reorganized the business operations of IMN (Note 4(f)) to improve efficiencies and eliminate redundant activities on a company-wide basis. The restructuring affected all cost centers within the organization, but most significantly responsibilities at the sales and executive levels, as such activities were combined with our existing business operations. Also as part of the restructuring plan, we relocated one of IMN's warehouses to a closer proximity of the manufacturing facility to improve efficiency. Of the $1.6 million in total exit costs, which include severance costs of involuntarily terminated employees and costs to vacate the warehouse, $1.3 million were paid and $0.3 million remained unpaid as of December 31, 2004. The total number of involuntarily terminated employees was 47, all of which have been terminated as of December 31, 2003.

As a result of the acquisition of the Unipath business from Unilever Plc in 2001, we reorganized the operations of the Unipath business for purposes of improving efficiencies and achieving economies of scale on a company-wide basis. Such reorganization affected all major cost centers at the operations in England. Additionally, most business activities of the U.S. division were merged into our existing U.S. businesses. 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 $2.3 million. During 2002, the Company finalized all restructuring activities and recorded an additional $1.8 million in exit costs. The additional exit costs were recorded as adjustments to the Unipath business purchase price. As of December 31, 2004, $1.4 million, adjusted for foreign exchange effect, in exit costs remained unpaid.

(19) Guarantor Financial Information

We issued $150.0 million in Bonds to qualified institutional buyers in reliance on Rule 144A under the Securities Act of 1933, as amended (the "Securities Act") and outside the United States in

compliance with Regulation S of the Securities Act (Note 6(b)). Our payment obligations under the Bonds are guaranteed by all of our domestic subsidiaries (the "Guarantor Subsidiaries") as of December 31, 2004. The guarantee is full and unconditional. Separate financial statements of the Guarantor Subsidiaries are not presented because we have determined that they would not be material to investors in the Bonds. The following supplemental financial information sets forth, on a consolidating basis, the statements of operations and cash flows for each of the three years in the period ended December 31, 2004 and the balance sheets as of December 31, 2004 and 2003 for our company (the "Issuer"), the Guarantor Subsidiaries and our other subsidiaries (the "Non-Guarantor Subsidiaries"). The supplemental financial information reflects our investments and the Guarantor Subsidiaries' investments in the Guarantor and Non-Guarantor Subsidiaries using the equity method of accounting.

We have extensive transactions and relationships between various members of 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.

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

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF OPERATIONS
For the Year Ended December 31, 2004
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	$ 20,842	$ 217,051	$ 180,685	$ (50,227)	$ 368,351
License revenue		114	8,445		8,559
Net Revenue	20,842	217,165	189,130	(50,227)	376,910
Cost of sales	20,182	164,944	92,713	(50,291)	227,548
Gross profit	660	52,221	96,417	64	149,362
Operating expenses:					
Research and development	246	3,088	28,620		31,954
Sales and marketing	1,899	25,377	30,681		57,957
General and administrative	10,982	14,716	27,009		52,707
Total operating expenses	13,127	43,181	86,310		142,618
Operating (loss) income	(12,467)	9,040	10,107	64	6,744
Equity in earnings of subsidiaries, net of tax	9,752			(9,752)	
Interest expense, including amortization of discounts	(15,345)	(5,699)	(5,893)	4,823	(22,114)
Other income, net	4,870	1,857	1,503	(4,823)	3,407
(Loss) income before income taxes	(13,190)	5,198	5,717	(9,688)	(11,963)
Provision (benefit) for income taxes	1,048	1,276	(458)	409	2,275
Net (loss) income	$ (14,238)	$ 3,922	$ 6,175	$ (10,097)	$ (14,238)

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF OPERATIONS
For the Year Ended December 31, 2003
(restated)
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	$ 22,717	$ 167,386	$ 135,222	$ (38,341)	$ 286,984
License revenue		401	9,327		9,728
Net Revenue	22,717	167,787	144,549	(38,341)	296,712
Cost of sales	19,964	121,161	64,220	(37,174)	168,171
Gross profit	2,753	46,626	80,329	(1,167)	128,541
Operating expenses:					
Research and development	486	1,652	22,142		24,280
Sales and marketing	2,062	24,616	25,826		52,504
General and administrative	7,397	10,101	17,954		35,452
Stock-based compensation	447				447
Total operating expenses	10,392	36,369	65,922		112,683
Operating (loss) income	(7,639)	10,257	14,407	(1,167)	15,858
Equity in earnings of subsidiaries, net of tax	16,169			(16,169)	
Interest expense, including amortization of discounts	(3,711)	(3,814)	(3,264)	1,078	(9,711)
Other income, net	5,239	570	1,710	(1,078)	6,441
Income before income taxes	10,058	7,013	12,853	(17,336)	12,588
Provision for income taxes	498	2,337	37	156	3,028
Net income	$ 9,560	$ 4,676	$ 12,816	$ (17,492)	$ 9,560

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF OPERATIONS
For the Year Ended December 31, 2002
(restated)
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	$ 22,639	$ 91,746	$ 118,055	$ (32,041)	$ 200,399
License revenue			6,405		6,405
Net Revenue	22,639	91,746	124,460	(32,041)	206,804
Cost of sales	18,616	68,018	57,411	(29,392)	114,653
Gross profit	4,023	23,728	67,049	(2,649)	92,151
Operating expenses:					
Research and development	1,074	116	13,281		14,471
Sales and marketing	2,229	15,997	21,318		39,544
General and administrative	6,269	5,426	16,371		28,066
Charge related to asset impairment		12,682			12,682
Stock-based compensation	10,625				10,625
Total operating expenses	20,197	34,221	50,970		105,388
Operating (loss) income	(16,174)	(10,493)	16,079	(2,649)	(13,237)
Equity in (losses) of subsidiaries, net of tax	(21,353)			21,353	
Interest expense, including amortization of discounts	(8,039)	(1,285)	(6,153)	408	(15,069)
Other income (expense), net	11,088	133	(1,699)	(408)	9,114
(Loss) income before income taxes	(34,478)	(11,645)	8,227	18,704	(19,192)
Provision for income taxes	305	621	2,546	(29)	3,443
(Loss) income before cumulative effect of a change in accounting principle	(34,783)	(12,266)	5,681	18,733	(22,635)
Cumulative effect of a change in accounting principle (Note 5)		(12,148)			(12,148)
Net (loss) income	$ (34,783)	$ (24,414)	$ 5,681	$ 18,733	$ (34,783)

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING BALANCE SHEET
December 31, 2004
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
ASSETS					
Current Assets:					
Cash and cash equivalents	$ 12	$ 3,551	$ 13,193	$	$ 16,756
Accounts receivable, net of allowances	2,660	36,273	22,414		61,347
Inventories	6,340	40,061	19,815	(6,073)	60,143
Deferred tax assets			2,819		2,819
Prepaid expenses and other current assets	1,278	2,034	6,289		9,601
Intercompany receivables	54,358	10,015	14,145	(78,518)	
Total current assets	64,648	91,934	78,675	(84,591)	150,666
Property, plant and equipment, net	2,808	27,591	36,381		66,780
Goodwill	17,672	108,842	94,641		221,155
Other intangible assets with indefinite lives		12,420	38,122		50,542
Core technology and patents, net	2,533	6,009	31,785		40,327
Other intangible assets, net		20,522	7,158		27,680
Deferred financing costs, net, and other non-current assets	6,452	1,710	994		9,156
Deferred tax assets			826	46	872
Investment in subsidiaries	264,539	(966)		(263,573)	
Intercompany notes receivable	114,439	15,089		(129,528)	
Total assets	$ 473,091	$ 283,151	$ 288,582	$ (477,646)	$ 567,178
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Current portion of long-term debt	$	$	$ 88		$ 88
Current portion of capital lease obligations		461	6		467
Accounts payable	1,754	19,497	11,094		32,345
Accrued expenses and other current liabilities	12,408	17,298	22,180		51,886
Intercompany payables	13,640	15,964	48,914	(78,518)	
Total current liabilities	27,802	53,220	82,282	(78,518)	84,786
Long-term liabilities:					
Long-term debt	169,256	20,000	12		189,268
Capital lease obligations		1,397	4		1,401
Deferred tax liabilities	1,352	3,821	7,423		12,596
Other long-term liabilities		29	4,417		4,446
Intercompany notes payable		53,221	76,307	(129,528)	
Total long-term liabilities	170,608	78,468	88,163	(129,528)	207,711

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Series A redeemable convertible preferred stock					
Stockholders' equity	274,681	151,463	118,137	(269,600)	274,681
Total liabilities and stockholders' equity	$ 473,091	$ 283,151	$ 288,582	$ (477,646)	$ 567,178

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING BALANCE SHEET
December 31, 2003
(restated)
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
ASSETS					
Current Assets:					
Cash and cash equivalents	$ 1,708	$ 11,315	$ 11,599	$	$ 24,622
Accounts receivable, net of allowances	3,915	36,071	15,432		55,418
Inventories	4,463	32,865	16,232	(6,137)	47,423
Deferred tax assets			1,178		1,178
Prepaid expenses and other current assets	1,365	1,995	7,239		10,599
Intercompany receivables	6,073	11,785	8,674	(26,532)	
Total current assets	17,524	94,031	60,354	(32,669)	139,240
Property, plant and equipment, net	1,199	28,032	28,542		57,773
Goodwill	48,704	73,388	94,641		216,733
Other intangible assets with indefinite lives		9,092	37,627		46,719
Core technology and patents, net	8,193	294	29,455		37,942
Other intangible assets, net	6,437	15,399	10,843		32,679
Deferred financing costs, net, and other non-current assets	2,015	4,515	927		7,457
Deferred tax assets	(295)	794	957		1,456
Investment in subsidiaries	204,553			(204,553)	
Intercompany notes receivable	120,918	94,208		(215,126)	
Total assets	$ 409,248	$ 319,753	$ 263,346	$ (452,348)	$ 539,999
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Current portion of long-term debt	$	$ 13,600	$ 455	$	$ 14,055
Current portion of capital lease obligations		452	5		457
Accounts payable	4,448	19,723	13,835		38,006
Accrued expenses and other current liabilities	8,641	17,578	14,903		41,122
Intercompany payables	6,512	8,016	12,008	(26,536)	
Total current liabilities	19,601	59,369	41,206	(26,536)	93,640
Long-term liabilities:					
Long-term debt	34,056	92,899	32,883		159,838
Capital lease obligations		1,823	8		1,831
Deferred tax liabilities		3,118	6,000		9,118
Other long-term liabilities			3,307		3,307
Intercompany notes payable	83,326	57,186	74,611	(215,123)	
Total long-term liabilities	117,382	155,026	116,809	(215,123)	174,094
	6,185				6,185

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Series A redeemable convertible preferred stock					
Stockholders' equity	266,080	105,358	105,331	(210,689)	266,080
Total liabilities and stockholders' equity	$ 409,248	$ 319,753	$ 263,346	$ (452,348)	$ 539,999

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF CASH FLOWS
For the Year Ended December 31, 2004
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Operating Activities:					
Net (loss) income	$ (14,238)	$ 3,922	$ 6,175	$ (10,097)	$ (14,238)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:					
Equity in earnings of subsidiaries, net of tax	(9,752)			9,752	
Interest expense related to amortization of noncash original issue discount, non cash beneficial conversion feature and deferred financing costs	1,181	3,282	466		4,929
Noncash gain related to interest rate swap agreement	(695)				(695)
Noncash stock-based compensation expense					
Noncash value on settlement of litigation			(495)		(495)
Depreciation and amortization	1,051	8,884	13,565		23,500
Deferred income taxes	1,056	1,497	(733)	412	2,232
Other noncash items		40	(76)		(36)
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net	1,255	(1,049)	(4,301)		(4,095)
Inventories	(1,497)	(7,125)	(1,826)	(64)	(10,512)
Prepaid expenses and other current assets	86	(54)	2,084		2,116
Intercompany payable (receivable)	10,082	(12,268)	2,778	(592)	
Accounts payable	(2,773)	(283)	(3,841)		(6,897)
Accrued expenses and other current liabilities	6,925	(16)	5,221		12,130
Other non-current liabilities		29	327		356
Net cash (used in) provided by operating activities	(7,319)	(3,141)	19,344	(589)	8,295

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF CASH FLOWS (continued)
For the Year Ended December 31, 2004
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Investing Activities:					
Purchases of property, plant and equipment	(1,635)	(7,836)	(10,918)		(20,389)
Proceeds from sale of property, plant and equipment		244	141		385
Cash paid to acquire certain assets from Abbott	(1,566)		(68)		(1,634)
Cash paid to acquire ABI, net of cash received	(530)				(530)
Cash paid to acquire Ostex, Inc, net of cash received	22	(1,437)			(1,415)
Cash paid to acquire Wampole Divison of MedPoint Inc					
Cash paid to acquire IVC Industries, net of cash received	(256)				(256)
Cash paid to acquire Unipath, net of cash received			(50)		(50)
Cash paid to acquire other businesses and intellectual property	(2,461)	(187)	(5,876)		(8,524)
(Increase) Decrease in other assets	(1,069)	79	(899)		(1,889)
Net cash used in investing activities	(7,495)	(9,137)	(17,670)		(34,302)
Cash Flows from Financing Activities:					
Cash paid for financing costs	(5,055)	(430)	(186)		(5,671)
Proceeds from issuance of common stock, net of issuance costs	1,905				1,905
Net proceeds from line of credit	77	(7,682)	(23,225)		(30,830)
Proceeds from issuance of senior subordinated notes	150,000				150,000
Repayments of notes payable	(9,000)	(78,817)	(10,013)		(97,830)
Principal payments of capital lease obligations		(473)	(4)		(477)
Intercompany notes (receivable) payable	(124,809)	91,949	32,860		
Net cash provided by (used in) financing activities	13,118	4,547	(568)		17,097
Foreign exchange effect on cash and cash equivalents		(33)	488	589	1,044
Net (decrease) increase in cash and cash equivalents	(1,696)	(7,764)	1,594		(7,866)
Cash and cash equivalents, beginning of year	1,708	11,315	11,599		24,622
Cash and cash equivalents, end of year	$ 12	$ 3,551	$ 13,193	$	$ 16,756

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF CASH FLOWS
For the Year Ended December 31, 2003
(restated)
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Operating Activities:					
Net income	$ 9,560	$ 4,676	$ 12,816	$ (17,492)	$ 9,560
Adjustments to reconcile net income to net cash (used in) provided by operating activities:					
Equity in earnings of subsidiaries, net of tax	(16,169)			16,169	
Interest expense related to amortization of noncash original issue discount, non cash beneficial conversion feature and deferred financing costs	454	587	524		1,565
Noncash gain related to interest rate swap agreement	(528)				(528)
Noncash stock-based compensation expense	447				447
Depreciation and amortization	958	6,728	8,749		16,435
Deferred income taxes	50	(120)	725	157	812
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net	749	(8,760)	(1,196)	(385)	(9,592)
Inventories	295	(1,644)	(1,871)	1,166	(2,054)
Prepaid expenses and other current assets	(336)	(88)	(3,678)		(4,102)
Intercompany payable (receivable)	851	3,851	(4,764)	62	
Accounts payable	(737)	2,840	3,282	1,330	6,715
Accrued expenses and other current liabilities	3,885	(6,876)	(6,466)		(9,457)
Net cash (used in) provided by operating activities	(521)	1,194	8,121	1,007	9,801

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF CASH FLOWS (continued)
For the Year Ended December 31, 2003
(restated)
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Investing Activities:					
Purchases of property, plant and equipment	(497)	(3,809)	(6,829)		(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	(402)	79		396
Net cash used in investing activities	(17,346)	(31,366)	(40,418)		(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		19,149	182		19,331
Proceeds from borrowings under notes payable		57,575	46		57,621
Repayments of notes payable		(5,392)	(393)		(5,785)
Principal payments of capital lease obligations		(651)			(651)
Intercompany notes payable (receivable)	13,400	(42,000)	28,600		
Net cash provided by (used in) financing activities	16,571	25,029	28,386		69,986
Foreign exchange effect on cash and cash equivalents		(196)	4,500	(1,007)	3,297
Net (decrease) increase in cash and cash equivalents	(1,296)	(5,339)	589		(6,046)
Cash and cash equivalents, beginning of year	3,004	16,654	11,010		30,668
Cash and cash equivalents, end of year	$ 1,708	$ 11,315	$ 11,599	$	$ 24,622

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF CASH FLOWS
For the Year Ended December 31, 2002
(restated)
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Operating Activities:					
Net (loss) income	$ (34,783)	$ (24,414)	$ 5,681	$ 18,733	$ (34,783)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:					
Equity in losses of subsidiaries, net of tax	21,353			(21,353)	
Interest expense related to amortization of noncash original issue discount, noncash beneficial conversion feature and deferred financing costs	4,780	128	2,591		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	3,370	6,368		10,308
Deferred income taxes	469	291	26		786
Other noncash items			354		354
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net	(5,232)	3,864	2,595		1,227
Inventories	(3,500)	(5,185)	4,465	2,130	(2,090)
Prepaid expenses and other current assets	1,348	827	(1,707)		468
Intercompany (receivable) payable	(9,414)	1,996	(6,825)	14,243	
Accounts payable	3,185	3,548	2,114		8,847
Accrued expenses and other current liabilities	(11,489)	(1,741)	2,183	489	(10,558)
Net cash (used in) provided by operating activities	(30,465)	7,514	17,845	14,242	9,136

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF CASH FLOWS (continued)
For the Year Ended December 31, 2002
(restated)
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Investing Activities:					
Purchases of property, plant and equipment	(189)	(625)	(5,263)		(6,077)
Proceeds from sale of property, plant and equipment		1,278	267		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) provided by investing activities	(81,928)	5,033	(9,749)		(86,644)
Cash Flows from Financing Activities:					
Cash paid for financing costs	(1,207)	(964)	(1,804)		(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
Proceeds from borrowings under notes payable	35,000	16,250	33,171		84,421
Repayments of notes payable	(20,000)	1,512	(63,752)		(82,240)
Principal payments of capital lease obligations		(494)			(494)
Intercompany notes payable (receivable)	6,652	(19,187)	12,535		
Net cash provided by (used in) financing activities	76,334	(234)	(19,850)		56,250
Foreign exchange effect on cash and cash equivalents		(1,488)	15,632	(14,242)	(98)
Net (decrease) increase in cash and cash equivalents	(36,059)	10,825	3,878		(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	$ 16,654	$ 11,010	$	$ 30,668

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