INVERNESS MEDICAL INNOVATIONS INC
Form 10-K
March 16, 2006

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

ANNUAL REPORT 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, 2005

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 Securities Exchange Act of 1934 (the "Exchange 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 Exchange Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes o No ý

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes o No ý

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act 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. o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer o Accelerated filer ý Non-accelerated filer o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No ý

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, 2005 (the last business day of the registrant's most recently completed second fiscal quarter) was $525,155,522. 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 14, 2006, the registrant had 31,287,885 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 May 1, 2006 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 Item 1A. entitled "Risk Factors," which begins on page 11 of 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

Private Placement of 3,400,000 Shares

On February 8 and 9, 2006, we sold 3,400,000 shares of our common stock to funds affiliated with 14 accredited institutional investors in a private placement at $24.41 per share. Net proceeds from the private placement were $79.3 million after subtracting aggregate placement fees and commissions of approximately $3.7 million.

Agreement to Acquire Certain Assets from ACON Laboratories

On February 24, 2006, we entered into a definitive agreement with ACON Laboratories, Inc. and certain affiliated entities to acquire (i) the assets of ACON's business of researching, developing, manufacturing, marketing and selling lateral flow immunoassay and directly-related products in the United States, Canada, Europe (excluding Russia, the former Soviet Republics that are not part of the European Union and Turkey), Israel, Australia, Japan and New Zealand and (ii) all of the capital stock of entities owning a newly-constructed manufacturing facility currently undergoing validation in Hangzhou, China.

The aggregate purchase price for the acquired business, including the new manufacturing facility, will be between $140.0 million and $175.0 million based upon a multiple of revenue and pre-tax profits of the acquired business, though we have agreed to acquire up to $4.0 million in indebtedness related to the new manufacturing facility. The aggregate purchase price is expected to be paid based on completion of certain milestones related to achievement of functional manufacturing operations in certain territories. Such purchase price shall be paid by issuing an aggregate of up to $50.0 million of our common stock, but in no event more than 2,130,000 shares, with the remainder of the purchase price being paid in cash.

The transaction is subject to the consent of our lenders and other ordinary and customary closing conditions, including certain regulatory approvals. The acquisition of the lateral flow business described above is expected to close in the first or second quarter of 2006 and the acquisition of the manufacturing facility is expected to close by the end of the second quarter of 2006.

Acquisition of CLONDIAG chip technologies GmbH

On February 28, 2006, we acquired 67.45% of the capital stock of CLONDIAG chip technologies GmbH, a private company located in Jena in Germany which has developed a multiplexing technology for nucleic acid and immunoassay based diagnostics, in exchange for 218,502 shares of our common stock and approximately $3.1 million in cash. We also agreed to settle obligations totaling approximately $10.0 million during the first quarter of 2006, primarily using cash. Under our agreement with the CLONDIAG shareholders, we will acquire the remaining 32.55% of the capital stock of CLONDIAG on or about August 31, 2006 for an additional $4.9 million based on current exchange rates. The agreement also calls for contingent consideration totaling approximately $8.9 million consisting of 224,316 shares of common stock and approximately $3.0 million of cash or stock in the event that four specified products are developed on CLONDIAG's platform technology during the three years following the date of the initial stock purchase.

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 16 of the "Notes to Consolidated Financial Statements," which are included elsewhere in this report.

Products

Consumer Diagnostic Products. Our current consumer diagnostic products currently 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, nutritional supplements and over-the-counter drug products 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.

Our professional diagnostics products, which are generally marketed under the trade name, Inverness Medical Professional Diagnostics, 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. Outside of the United States we also develop and market rapid HIV tests. Our rapid tests are qualitative, visually-interpreted rapid diagnostic tests that are used in point-of-care environments where a rapid response is desired or where the volume of testing is too low to warrant high-volume methods. Our rapid tests are sold under the brand names Clearview, Wampole, NOW, BinaxNOW, Acceava, BioStar OIA, SureStep, Signify and TestPack, and our HIV products, which are sold outside of the United States, are sold under our Determine, DainaScreen and Orgenics brand names.

Ischemia Test. Our Albumin Cobalt Binding, or ACB, test is a clinical chemistry assay that detects Ischemia Modified Albumin, or IMA, by measuring the cobalt binding capacity of albumin in a patient serum sample. IMA concentrations in blood rise quickly and remain elevated during an ischemic event, returning to normal level several hours after cessation of ischemia. IMA can be used in conjunction with electrocardiogram (ECG) and troponin as an aid to rule out acute coronary syndrome at presentation-saving time, resources and money. ACB test reagents are used by clinical laboratories in conjunction with clinical chemistry instruments sold by third parties, including Roche Diagnostics.

ELISA Products. We offer over 70 enzyme linked immunosorbent assays (ELISA) tests for a wide variety of infectious and autoimmune diseases, as well as a full line of automated instrumentation for processing ELISA assays. Our ELISA products are generally marketed under our Wampole brand.

AtheNA Multi-Lyte Test System. We are the exclusive U.S. distributor of the AtheNA Multi-Lyte Test System, which is capable of simultaneously performing multiple assays from a single patient sample in the areas of autoimmune and infectious disease. The AtheNA Multi-Lyte Test System 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 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. We also sell Crystal Clear, the leading brand in Australia. 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 much of Western Europe using our own sales managers and a network of sales representatives. In other areas of the world, including Japan, Canada, Australia and the rest of Europe, our consumer diagnostic products are sold though distribution contracts. Private label and contract manufacturing arrangements accounted for 27% of our consumer diagnostics business' net product sales for 2005.

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 2005, based on net product sales, together accounted for almost 61% 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, the United Kingdom, Spain, Germany and France, we distribute our professional diagnostic products to hospitals, reference laboratories, physician's offices and other point-of-care settings through our own sales forces and distribution networks. In all other major markets around the world we utilize third party distributors to sell our products. We also distribute products for other parties, primarily in Germany and, since October 2005, in Spain, through our subsidiaries, Inverness Medical Deutschland and Inverness Medical Iberica.

Under the terms of our acquisition of the Determine/DainaScreen products from Abbott Laboratories in June 2005, Abbott distributes our Determine/DainaScreen products, which are sold outside of the United States, for up to 32 months in order to allow us time to obtain various marketing or sales licenses in the many countries where these products are sold. Abbott acts as our exclusive distributor, although we have certain rights to terminate the distribution arrangement on a country by country basis in the future. We also sell these products to Abbott as the exclusive supplier of its global "Access to HIV Care" program, through which Abbott provides free or low-cost testing products for HIV testing in underdeveloped countries around the world.

Manufacturing

Consumer Diagnostic Products. We manufacture nearly all of our disposable consumer diagnostic products at our facilities in Bedford, England; Shanghai, China and San Diego, California. These

facilities are each ISO certified and registered with the United States Food and Drug Administration. 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 44% of the professional diagnostic products that we sell, based on net product sales for the fiscal year ended December 31, 2005 were manufactured by third parties. We manufacture the remainder, including substantially all of our Clearview, NOW, BinaxNOW, BioStar OIA, SureStep, Signify and TestPack products, ourselves at our facilities in Shanghai, China; Bedford, UK; Yavne, Israel; Scarborough, Maine; Louisville, Colorado and San Diego, California. We also manufacture the Determine/DainaScreen HIV products that we acquired from Abbott in June 2005 at Abbott's facility in Matsudo, Japan in space rented from Abbott under a manufacturing and support services agreement entered into in connection with the acquisition.

Research and Development

A significant portion our budget for research and development currently is allocated to the development of cardiovascular disease management products. On February 25, 2005, we entered into a co-development agreement with ITI Scotland Limited ("ITI"), whereby ITI agreed to provide us with approximately 30 million British Pounds Sterling (or $51.8 million at December 31, 2005) 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 ("the programs"). We agreed to invest 37.5 million British Pounds Sterling (or $64.7 million at December 31, 2005) in the programs over the next three years. Through our subsidiary, Stirling Medical Innovations Limited ("Stirling"), we established 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. ITI and Stirling will have exclusive rights to the developed technology in their respective fields of use.

The remainder of our research and development efforts is focused on expanding our range of product offerings and enhanced features for our lines of consumer and professional diagnostic products. Most of our research and development activities are carried out in Stirling, Scotland and Bedford, England, but we also conduct research and development at our facilities in Scarborough, Maine; Yavne, Israel; Farum, Denmark and Jena, Germany. The Jena facility was acquired in February 2006 as part of our acquisition of CLONDIAG chip technologies GmbH.

Foreign Operations

Our business relies heavily on our foreign operations. Four of our eight current manufacturing facilities are outside the United States, including our primary consumer diagnostic products manufacturing facilities in Bedford, England and Shanghai, China, and the manufacturing operation in Matsudo, Japan, which is conducted out of a facility owned by Abbott. Approximately 42% of our net revenues were generated from outside of the United States during 2005. Our Clearblue products, pregnancy tests in particular, have historically been much stronger brands outside the United States, with 68% of our net product sales of Clearblue products coming from outside the United States during 2005. Our TestPack and Determine/DainaScreen product lines are 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 and we have agreed to acquire the lateral flow business of ACON Laboratories for most major markets and expect that acquisition to close during the first or second quarter of 2006. Our competitors for the sale of fertility/ovulation prediction tests include Church & Dwight, Princeton BioMeditech and Syntron. 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, as is our Crystal Clear brand in Australia, 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 Pharmaca, 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, although we have agreed to acquire ACON's lateral flow business for most major markets and expect that acquisition to close during the first or second quarter of 2006. 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 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.

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 Remel and Biokit. 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, 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 in Item 1A. entitled "Risk Factors" on pages 11 through 25 of this report.

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 had become subject to the FDA's Application Integrity Policy. As a result, the FDA is obligated to 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. ABI is not restricted from introducing new tests outside of the United States, or from selling products in the United States based on any existing 510(k)s. However, ABI withdrew certain 510(k)s related to its drugs of abuse products and a Class III recall (based on our assessment that any hazard to the public health is unlikely) was undertaken for the corresponding products. ABI is in the final stages of both an internal and external audit, and is committed to taking any actions required by those audits in order to fulfill its regulatory obligations.

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, 2006, we had approximately 2,360 employees, of which 957 employees are located in the United States. In addition, we utilize the services of temporary 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 1A. RISK FACTORS

The risk factors 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 your investment in our securities. This section includes or refers to certain forward-looking statements; you should read the explanation of the qualifications and limitations on such forward-looking statements beginning on pages 2 and 30 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, 2005, we had approximately $262.5 million in aggregate principal indebtedness outstanding, of which $93.2 million is secured indebtedness, and $11.0 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 $150.0 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, 2005 and 2004, we recorded $21.8 million and $22.1 million, respectively, of interest expense related to our indebtedness, which included $2.3 million and $4.2 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, and potentially from other debt or equity offerings. Our ability to meet our expenses thus depends on our future performance, which will be affected by financial, business, economic and other factors. We will not be able to control many of these factors, such as economic conditions in the markets in which we operate and pressure from competitors. We cannot be certain that our cash flow will be sufficient to allow us to pay principal and interest on our debt and meet our other obligations.

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

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

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

incur additional indebtedness;

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

acquire other businesses;

make investments;

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

enter into transactions with affiliates;

raise additional capital;

make capital or finance lease expenditures;

dispose of or encumber assets; and

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

These restrictions may limit our ability to pursue business opportunities or strategies that we would otherwise consider to be in our best interests. 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, the rapid diagnostics business that we acquired from Abbott Laboratories in 2003, or the 2003 Abbott rapid diagnostics business, Ischemia, Inc., or Ischemia, Binax, Inc., or Binax, the Determine/DainaScreen business that we acquired from Abbott Laboratories in 2005, or the Determine business, Thermo BioStar Inc, or BioStar, Innogenetics Diagnostica y Terapeutica S.A.U., or IDT, and CLONDIAG chip technologies GmbH, or Clondiag. In addition, we are required to obtain our lenders' consent in order to consummate our recently announced agreement to acquire certain assets from ACON Laboratories, or the ACON acquisition.

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

As of December 31, 2005, we had approximately $89.0 million of indebtedness outstanding under our senior credit facility and approximately $11.0 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 we have attempted to integrate, or we are in the process of integrating, 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, the 2003 Abbott rapid diagnostics business, Ischemia, Binax, the Determine business, BioStar, IDT and Clondiag. 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 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, the 2003 Abbott rapid diagnostics product lines, Ischemia, Binax, the Determine business, BioStar, IDT and Clondiag, we have recorded, or expect to record, 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 most of our Clearblue and Clearview products, serves as our primary research and development center and serves as the administrative center for our European operations. We also use this facility to manufacture the digital 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 consented to, 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 approximately ten 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. In addition, we manufacture the products acquired with the Determine business from a facility in Matsudo, Japan that is made available to us, and with support services provided by, Abbott Laboratories. 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.

Our failure to meet strict regulatory requirements could require us to pay fines, incur other costs 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. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and profits.

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 had become subject to the FDA's Application Integrity Policy. As a result, the FDA is obligated to 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. ABI is not restricted from introducing new tests outside of the United States, or from selling products in the United States based on any existing 510(k)s. However,

ABI withdrew certain 510(k)s related to its drugs of abuse products that were cited by the FDA, and a Class III recall (based on our assessment that any hazard to the public health is unlikely) was undertaken for the corresponding products. ABI is in the final stages of both an internal and external audit, and is committed to taking any actions required by those audits in order to fulfill its regulatory obligations. It is our understanding at this time 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 of the FDA action is uncertain, and may have a negative impact on our future sales and profits.

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

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

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

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

Our 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 2005, 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 legal proceedings.

We are involved in various legal proceedings arising out of our consumer diagnostics, nutritional supplements and professional diagnostics business. 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. 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 products businesses may suffer if we are unable to establish and maintain close working relationships with our customers.

For the years ended December 31, 2005 and 2004, approximately 58% and 65%, respectively, of our net product sales 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 accounted for approximately 61% of sales during 2005. 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 products businesses may suffer if Pfizer Inc. is unable to successfully market and sell its e.p.t pregnancy tests.

Under the terms of a manufacturing, packaging and supply agreement that we entered into 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, pursuant to the terms of a five-year supply agreement entered into in December 2003, as amended on June 1, 2005, we currently supply Pfizer with a digital version of its e.p.t brand pregnancy tests on an 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, 2005 and 2004, provided approximately 16% and 17%, 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 2005.

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

Approximately 42% and 40% of our net revenues were generated from outside the United States for the years ended December 31, 2005 and 2004, respectively. A significant number of our employees, including manufacturing, sales, support and research and development personnel, are located in foreign countries, including England, Japan, China, 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 operations are conducted outside the United States, in Bedford, England; Shanghai, China; Matsudo, Japan and Yavne, Israel. We have consolidated much of our cardiovascular related research and development in Scotland and ultimately we intend to establish a significant manufacturing operation there. Approximately 42% and 40% of our net revenues were generated from outside the United States for the years ended December 31, 2005 and 2004, respectively. Our Clearblue pregnancy test product sales have historically been much stronger outside the United States, with 68% of net product sales of these products coming from outside the United States during the year ended December 31, 2005. In addition, the Abbott rapid diagnostics business, which we acquired on September 30, 2003, generates a majority of its sales outside the United States, and all of the revenues of the Determine business are derived outside of the United States. Because of our foreign operations and foreign sales, we face exposure to movements in foreign currency exchange rates. Our primary exposures are related to the operations of our European subsidiaries. With our recent acquisition of the Determine business and the establishment of our manufacturing facility in Shanghai, we anticipate that our currency exposures related to the yen and the Chinese yuan will become more significant to our results than in prior periods. Should it be consummated, our pending acquisition of the rapid diagnostic business of ACON Laboratories for most major markets, which includes the acquisition of a major manufacturing facility in China, will also increase our exposure to the Chinese yuan. 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.

In December 2005, we learned that the Securities and Exchange Commission, or the SEC, had issued a formal order of investigation in connection with the previously disclosed revenue recognition matter at one of our diagnostic divisions. We cannot predict what the outcome of this investigation will be.

In December 2005, we learned that the SEC had issued a formal order of investigation in connection with the previously disclosed revenue recognition matter at one of our diagnostic divisions, and we subsequently received a subpoena for documents. We believe that we fully responded to the

subpoena and we will continue to fully cooperate with the SEC's investigation. We cannot predict whether the SEC will seek additional information or what the outcome of its investigation will be.

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.

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 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 Industries, Inc. in March 2002, Wampole in September 2002, Ostex in June 2003, ABI in August 2003, the 2003 Abbott rapid diagnostics product lines in September 2003, Binax and Ischemia in March 2005, the Determine business in June 2005, BioStar and IDT in September 2005 and Clondiag in February 2006. 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.

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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 2005, the sales price of our common stock ranged from $20.49 to $29.99, and during 2004, the sales price of our common stock ranged from $14.75 to $25.50. 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None

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 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; Scarborough, Maine; Louisville, Colorado; San Diego, California; Yavne, Israel; Matsudo, Japan; Freehold, New Jersey and Irvington, New Jersey. We currently manufacture a portion of our consumer products out of approximately 25,000 square feet of space in Shanghai, China made available by our joint venture partner. We manufacture certain of our professional diagnostic products out of a 64,000 square foot facility that we lease in Scarborough, Maine, a 75,000 square foot facility that we lease in Louisville, Colorado, and a 40,000 square foot facility that we lease in San Diego, California. We house the development, manufacturing, administrative and marketing operations related to our Orgenics professional diagnostic products in a leased facility of approximately 10,000 square feet in Yavne, Israel. The products that we acquired from Abbott in June 2005 our manufactured by us in Matsudo, Japan in 19,000 square feet of space rented from Abbott under a manufacturing and support services agreement entered into in connection with the acquisition. 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. Consistent with our previously announced timeline, we have recently ceased operations at our facility in Galway, Ireland and we have sold the building that we owned there.

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), Scotland (Stirling), Canada (Boucherville), Denmark (Farum), Belgium (Sint-Niklaas), Germany (Jena, Cologne and Munich), France (Paris), Spain (Barcelona), Australia (Beaumaris) and Sweden (Lund), and our Orgenics products are sold through small sales offices in France, Brazil and several other countries.

ITEM 3. LEGAL PROCEEDINGS

We currently are not a party to any material pending legal 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. These suits can be expensive and result in counterclaims challenging the validity of our patents and other rights.

In addition, in December 2005, we learned that the SEC's Enforcement Division had issued a formal order of investigation in connection with the previously disclosed revenue recognition matter at one of our diagnostic divisions, and we subsequently received a subpoena for documents. We believe that we fully responded to the subpoena and we will continue to fully cooperate with the SEC's investigation. We cannot predict whether the SEC will seek additional information or what the outcome of its investigation will be.

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

No matters were submitted to a vote of our security holders during the fourth quarter of the year ended December 31, 2005.

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 2005 and 2004.

	High	Low
Fiscal 2005		
Fourth Quarter	$ 27.01	$ 21.90
Third Quarter	$ 29.51	$ 24.70
Second Quarter	$ 29.99	$ 21.25
First Quarter	$ 25.87	$ 20.49
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

On March 10, 2006, there were 638 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, 2005 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, 2005 and 2004 and for each of the three years in the period ended December 31, 2005 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, 2003 and 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 has 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, the Abbott rapid diagnostics business in September 2003, Binax and Ischemia in March 2005, the Determine business in June 2005, and BioStar and IDT in September 2005 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 1A. "Risk Factors" and Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations."

We have previously restated our consolidated financial statements as of and for the years ended December 31, 2004 and 2003 and for the first quarter of 2005 to correct errors under GAAP relating to the recognition of revenue. We determined that certain customers of one of our diagnostics divisions were provided return or exchange rights in connection with the sale of certain products for which reliable estimates of return or exchange had not been made, as a result of which the revenue associated with those sales should not have been recognized upon shipment to the customers under GAAP. As a result, we recorded $4.5 million in net revenue reversal with a $3.4 million gross margin and corresponding net loss impact spread over the quarters of 2004 and 2003 and an increase in both revenues and gross profit of $0.3 million in the first quarter of 2005. For further discussion of the restatement, see Note 2(p) of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

	2005	2004 (restated)	2003 (restated)	2002(2)	2001
			(in thousands, except per share data)		
Statement of Operations Data:					
Net product sales	$ 406,457	$ 365,432	$ 285,430	$ 200,399	$ 47,268
License and royalty revenue	15,393	8,559	9,728	6,405	
Net revenue	421,850	373,991	295,158	206,804	47,268
Cost of sales	269,538	226,987	167,641	114,653	26,662
Gross profit	152,312	147,004	127,517	92,151	20,606
Operating expenses:					
Purchased in-process research and development					6,980
Research and development	30,992	31,954	24,280	14,471	1,810
Sales and marketing	72,103	57,957	52,504	39,544	8,018
General and administrative	59,821	52,707	35,452	28,066	11,702
Charge related to asset impairment				12,682	
Stock-based compensation	169		447	10,625	10,441
Total operating expenses	163,085	142,618	112,683	105,388	38,951
Operating income (loss)	(10,773)	4,386	14,834	(13,237)	(18,345)
Interest expense and other expenses, net	(1,617)	(18,707)	(3,270)	(5,955)	(4,310)
(Loss) income from continuing operations before provision for income taxes	(12,390)	(14,321)	11,564	(19,192)	(22,655)
Provision for income taxes	6,819	2,275	2,911	3,443	2,134
(Loss) income from continuing operations	$ (19,209)	$ (16,596)	$ 8,653	$ (22,635)	$ (24,789)
(Loss) income from continuing operations available to common stockholders basic and diluted(1)	$ (19,209)	$ (17,345)	$ 7,695	$ (34,583)	$ (24,789)

	2005	2004	2003	2002(2)	2001
(Loss) income from continuing operations per common share(1):					
Basic(1)	$ (0.79)	$ (0.87)	$ 0.49	$ (3.48)	$ (3.89)
Diluted(1)	$ (0.79)	$ (0.87)	$ 0.44	$ (3.48)	$ (3.89)

	December 31,				
	2005	2004	2003	2002	2001
		(restated)	(restated)		
	(in thousands)				
Balance Sheet Data:					
Cash and cash equivalents	$ 34,270	$ 16,756	$ 24,622	$ 30,668	$ 52,024
Working capital	84,523	62,615	44,693	27,685	19,555
Total assets	791,166	568,269	540,529	356,495	278,521
Total debt	262,504	191,224	176,181	104,613	78,124
Redeemable convertible preferred stock			6,185	9,051	51,894
Total stockholders' equity	397,308	271,416	265,173	161,849	89,614

(1) (Loss) income available to common stockholders and basic and diluted (loss) income per common share are computed as described in Notes 2(k) and 12 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Further, for the year ended December 31, 2001, loss available to common stockholders and basic and diluted loss per common 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,				
	2005	2004	2003	2002	2001
		(restated)	(restated)		
	(in thousands, except per share data)				
(Loss) income from continuing operations	$ (19,209)	$ (16,596)	$ 8,653	$ (22,635)	$ (24,789)
Add back: Goodwill amortization, net of tax					398
Adjusted (loss) income from continuing operations	$ (19,209)	$ (16,596)	$ 8,653	$ (22,635)	$ (24,391)
Adjusted (loss) income from continuing operations available to common stockholders basic and diluted	$ (19,209)	$ (17,345)	$ 7,695	$ (34,583)	$ (24,391)
Adjusted (loss) income from continuing operations per common share(1):					
Basic	$ (0.79)	$ (0.87)	$ 0.49	$ (3.48)	$ (3.83)

	Year Ended December 31,				
Diluted	$ (0.79)	$ (0.87)	$ 0.44	$ (3.48)	$ (3.83)

(1) (Loss) income available to common stockholders and basic and diluted (loss) income per share are computed as described in notes 2(k) and 12 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Further, for the year ended December 31, 2001, loss available to common stockholders and basic and diluted loss 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

This report, 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. 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. Forward-looking statements in this Item 7. include, without limitation, statements regarding our expectations with respect to new product introductions, research and development expenditures, legal expenditures, our ability to deliver high quality products on an increasingly cost effective basis, anticipated growth in our professional diagnostics business, and our funding plans for our future working capital needs and commitments. 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 in Item 1A. entitled "Risk Factors," which begins on page 11 of this report, as well as those factors identified from time to time in our periodic filings with the Securities and Exchange Commission. We do not undertake any obligation to update any forward-looking statements. This report and, in particular, 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

Net revenues in 2005 of $421.9 million increased by $47.9 million, or 13%, from $374.0 million in 2004 as a result of acquisitions completed during 2005 and from higher license revenue principally resulting from a settlement and licensing arrangement that we entered into in April 2005. The acquisitions that we completed during 2005 were principally within our professional diagnostics segment. These acquisitions, including Binax in March 2005, the Determine rapid diagnostics business in June 2005, and BioStar and IDT in September 2005, added market leading flu and HIV tests to our expanding portfolio of rapid diagnostic tests and, in the case of IDT, expanded our direct distribution capabilities in Spain and Portugal. In addition to these acquisitions, we also expanded our depth in cardiology with the March 2005 acquisition of Ischemia. Ischemia's product is the only FDA-cleared *in vitro* diagnostic test targeted to the diagnosis of cardiac ischemia.

Gross profit increased by $5.3 million, or 4%, to $152.3 million in 2005 from $147.0 million in 2004 principally as a result of higher gross profit on increased license revenue and from gross profit earned on incremental revenues from acquired businesses. Offsetting these increases were a variety of charges discussed in more detail below totaling $8.1 million associated with the closing of one of our manufacturing facilities in 2005 and with charges associated with excess inventories and a product recall. Gross profit from our nutritional supplements business also decreased $6.0 million principally as a result of continuing pricing pressures in our private label nutritional supplements business. We will continue to evaluate opportunities to better integrate and utilize our existing and recently acquired or established manufacturing facilities in 2006 in an effort to continue to enhance our ability to deliver high quality products on an increasingly cost effective basis.

We continue to invest aggressively in research and development of new products and technologies. While reported research and development expense decreased by $1.0 million in 2005 from 2004, our expenditures in 2005 are reported net of $17.2 million arising from the co-development funding arrangement that we entered into with ITI Scotland in February 2005. Research and development

expense before considering the co-development funding was $48.2 million in 2005, an increase of $16.2 million from 2004. The increase in spending resulted in part from expenditures of $5.0 million in our professional diagnostics business associated with our acquisitions of Binax, BioStar and Ischemia. The remaining research and development spending primarily related to our continued significant investment in the development of products in the field of cardiology.

Results of Operations

Year Ended December 31, 2005 Compared to Year Ended December 31, 2004

Net Product Sales. Net product sales increased by $41.0 million, or 11%, to $406.5 million in 2005 from $365.4 million in 2004. Excluding the unfavorable impact of currency translation, net product sales in 2005 grew by approximately $41.8 million, or 11%, over 2004. Revenue increased as a result of our acquisitions in 2005: (i) Binax, acquired on March 31, 2005, contributed $18.4 million of such increase, (ii) the Determine rapid diagnostics business, acquired June 30, 2005, contributed revenues of $17.2 million, (iii) BioStar, acquired September 30, 2005, contributed revenues of $6.9 million, and (iv) various less significant acquisitions contributed an aggregate of $9.7 million of such increase.

Net Product Sales by Business Segment. Net product sales by business segment for 2005 and 2004 are as follows:

(in thousands)	2005	2004 (restated)	% Increase (decrease)
Consumer diagnostic products	$ 161,695	$ 158,706	2%
Vitamins and nutritional supplements	75,411	77,923	(3)%
Professional diagnostic products	169,351	128,803	31%
Total net product sales	$ 406,457	$ 365,432	11%

The currency adjusted increase in net product sales from our consumer diagnostic products was $3.5 million, or 2%, comparing 2005 to 2004. Of the currency adjusted increase, $1.9 million resulted from our acquisition of the consumer pregnancy test business of Advanced Clinical Systems Pty Ltd, or ACS, in January 2005. Organic growth, principally in the U.S., accounted for the remaining growth.

Net product sales of our vitamins and nutritional supplements decreased by $2.5 million, or 3%, comparing 2005 to 2004. The decrease was primarily our brand name nutritional business. 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 on an annual basis over the past several years. 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 currency adjusted increase in net product sales from our professional diagnostic products was $40.8 million, or 32%, comparing 2005 to 2004. Of the currency adjusted increase, revenue increased as a result of our acquisitions in 2005: (i) Binax contributed $18.4 million of such increase, (ii) the Determine rapid diagnostics business contributed revenues of $17.2 million, (iii) BioStar contributed revenues of $6.9 million, and (iv) various less significant acquisitions contributed an aggregate of $7.8 million of such increase.

Net Product Sales by Geographic Location. Net product sales by geographic location for 2005 and 2004 are as follows:

(in thousands)	2005	2004 (restated)	% Increase
United States	$ 234,229	$ 218,251	7%
Europe	108,981	98,136	11%
Other	63,247	49,045	29%
Total net product sales	$ 406,457	$ 365,432	11%

The growth in net product sales in all geographic regions resulted from the various acquisitions discussed above.

License and Royalty Revenue. License and royalty revenue represents license and royalty fees from intellectual property license agreements with third-parties. License and royalty revenue increased by $6.8 million, or 80%, to $15.4 million in 2005 from $8.6 million in 2004. The increase primarily relates to royalty revenues received as a result of the settlement and licensing arrangement that we entered into with Quidel Corporation in April 2005.

Gross Profit and Margin. Gross profit increased by $5.3 million, or 4%, to $152.3 million in 2005 from $147.0 million in 2004. The increase in gross profit was attributable to higher gross margins on the increased license revenue discussed above. Offsetting this increase was: (i) the inclusion in cost of sales of a $4.1 million charge principally associated with our decision to close our CDIL manufacturing facility, (ii) a charge of $2.4 million associated with a reserve established during the second quarter of 2005 at our Wampole subsidiary for excess quantities of certain raw materials and finished goods, including certain finished goods held at distributors but subject to rights of return, and (iii) a $1.6 million provision for returns and inventory reserve which was established as a result of our recall of the drugs of abuse diagnostic products during the first quarter of 2005, offset in part by the gross profit earned on increased professional diagnostics products revenue, as discussed above. Gross profit from our nutritional supplements business decreased $6.0 million from $8.8 million in 2004 to $2.7 million in 2005. Our private label nutritional supplements business has suffered from excess capacity in the industry and increasing price competition.

Overall gross margin was 36% in 2005 compared to 39% in 2004. Overall gross margin in 2005 was adversely affected by the $4.1 million charge associated with the CDIL closing, the $2.4 million Wampole inventory reserve, and the $1.6 million returns and inventory reserve associated with the drugs of abuse product recalls discussed above. Excluding these charges, gross margin was 38% for 2005.

Gross Profit from Net Product Sales by Business Segment. Gross profit from net product sales represents total gross profit less gross profit associated with license revenue. Gross profit from total net product sales decreased by $0.3 million to $141.5 million in 2005 from $141.8 million in 2004. Gross profit from net product sales by business segment for 2005 and 2004 are as follows:

(in thousands)	2005	2004 (restated)	% Increase (decrease)
Consumer diagnostic products	$ 76,515	$ 82,909	(8)%
Vitamins and nutritional supplements	2,738	8,775	(69)%
Professional diagnostic products	62,252	50,079	24%
Total gross profit from net product sales	$ 141,505	$ 141,763	0%

Gross profit from our consumer diagnostic product sales decreased by $6.4 million, or 8%, comparing 2005 to 2004. Included in cost of sales, and adversely effecting gross profit, was a $4.1 million charge principally associated with our decision to close our CDIL manufacturing facility.

Gross profit from our consumer diagnostic product sales was 47% for 2005 compared to 52% in 2004. Excluding the $4.1 million CDIL closure charge discussed above, gross margin from our consumer diagnostic products segment was 50% in 2005. The remaining decrease in gross margin from our consumer diagnostic product sales resulted from change in product mix.

Gross profit in our vitamins and nutritional supplements business decreased by $6.0 million, or 69%, comparing 2005 to 2004. Our private label nutritional supplements business has suffered from excess capacity in the industry which led to increasing price competition and generally decreasing margins. Revenue decreases in our brand named nutritional products also contributed to lower gross profit in 2005 than 2004.

Gross profit from our professional diagnostic products increased by $12.2 million, or 24%, comparing 2005 to 2004, principally as a result of gross profit earned on revenues from acquired businesses, as discussed above. Reducing gross margin for 2005 were a charge of $2.4 million associated with a reserve established during the second quarter of 2005 at our Wampole subsidiary for excess quantities of certain raw materials and finished goods, including certain finished goods held at distributors but subject to rights of return, and a $1.6 million provision for returns and inventory reserve which were established as a result of our recall of the drugs of abuse diagnostic products during the first quarter of 2005. Excluding these charges, gross profit from our professional diagnostic products segment increased by $16.2 million comparing 2005 to 2004.

Gross margin from our professional diagnostic product sales was 37% in 2005, compared to 39% in 2004. Excluding the $2.4 million Wampole inventory reserve and the $1.6 million drugs of abuse charge discussed above, gross margin from our professional diagnostic product sales was 39% for 2005.

Research and Development Expense. Research and development expense decreased by $1.0 million, or 3%, to $31.0 million in 2005 from $32.0 million in 2004. Research and development expense in 2005 is reported net of co-development funding of $17.2 million arising from the co-development funding arrangement that we entered into with ITI Scotland in February 2005. Research and development expense before considering the co-development funding was $48.2 million in 2005, an increase of $16.2 million from 2004.

The increase in spending resulted in part from expenditures of $5.0 million in our professional diagnostics business associated with our acquisitions of Binax, BioStar and Ischemia. The remaining research and development spending primarily related to our continued significant investment in the development of products in the field of cardiology.

Sales and Marketing Expense. Sales and marketing expense increased by $14.1 million, or 24%, to $72.1 million in 2005 from $58.0 million in 2004. Acquisitions completed during 2005 accounted for $8.3 million of the increase. Approximately $1.8 million of the increase in sales and marketing expense resulted from our increased advertising efforts to promote our premium consumer diagnostic products in 2005. The remaining increase in sales and marketing expense resulted from our expanded sales and marketing infrastructure to support the anticipated growth in our professional diagnostics business.

Sales and marketing expense as a percentage of net product sales increased to 18% in 2005 from 16% in 2004. The increase in sales and marketing expense as a percentage of net product sales primarily resulted from our investment in advertising efforts for our premium consumer diagnostic products and sales and marketing infrastructure to support our anticipated growth in the professional diagnostics business.

General and Administrative Expense. General and administrative expense increased by $7.3 million, or 14%, to $60.0 million in 2005 from $52.7 million in 2004. Acquisitions completed during 2005 accounted for $4.2 million of the increase. The remaining increase in general and administrative expense resulted from an increase in consulting and legal spending, due to the formal order of investigation in connection with the previously disclosed revenue recognition matter at Wampole and our active pursuits and defenses in litigations, including our lawsuits and settlements with Quidel and Princeton BioMeditech Corporation, or PBM. General and administrative expense as a percentage of net revenue was consistent in 2005 and 2004 at 14%.

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 in 2004, and the change in market value of our interest rate swap agreement of $0.7 million which did not qualify as a hedge for accounting purposes. Interest expense decreased by $0.3 million, or 1%, to $21.8 million in 2005 from $22.1 million in 2004. 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 $3.5 million in 2005. Such increase was primarily due to a higher average outstanding debt balance which was $215.3 million during 2005, compared to $194.4 million during 2004, primarily as a result of the borrowings to finance various acquisitions and operations, offset in part by funds raised from our sale of common stock in August 2005. Additionally, the 8.75% interest rate on the $150.0 million bonds, together with its 50 basis points interest penalty during a portion of the first quarter of 2005 due to the late registration of the related exchange offer, coupled with the impact of the increase in short-term interest rates which effected the borrowings under our senior credit facility, increased our average cash interest rate to 9.0% for 2005 from 8.8% for 2004. 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 facility.

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)	**2005**	**2004**
Interest income	$ 1,035	$ 1,050
Foreign exchange (losses) gains, net	(340)	(720)
Other	19,483	3,077
Total other income (expense), net	$ 20,178	$ 3,407

Included in other income (expense), net, for 2005 are the following items: (i) $15.0 million in income, being the portion of our settlement with Quidel relating to periods prior to 2005, (ii) an $8.4 million gain from a legal settlement of class action suit against several raw material suppliers in our vitamins and nutritional supplements business (iii) $2.6 million of income related to the value of an option received under a licensing arrangement, (iv) a $2.7 million charge related to a legal settlement of a nutritional segment commercial dispute arising from a distribution arrangement entered into in September 1996, and (v) a $4.3 million charge related to a legal settlement with PBM.

Included in other income (expense), net, 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.

Provision for Income Taxes. Provision for income taxes increased by $4.5 million, or 200%, to $6.8 million in 2005 from $2.3 million in 2004. The effective tax rate in 2005 was (55)%, compared to (16)% in 2004. The increase in the provision for income taxes from 2004 to 2005 is primarily related to taxes on foreign income. The primary components of the 2005 provision for income taxes related to the recognition of U.S. deferred tax liabilities for temporary differences between the book and tax bases of goodwill and certain intangible assets with indefinite lives and to taxes on foreign income. The amount related to the U.S. deferred tax liabilities is approximately $2.9 million. 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.

Net (Loss) Income. We incurred a net loss of $19.2 million in 2005, while we incurred a net loss of $16.6 million in 2004. 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 $17.3 million in 2004. Net loss per common share available to common stockholders was $0.79 per basic and diluted common share in 2005 as compared to net loss of $0.87 per basic and diluted common share in 2004. The net loss in 2005 and 2004 resulted from the various factors as discussed above. See Note 12 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, 2004 Compared to Year Ended December 31, 2003

Net Product Sales. Net product sales increased by $80.0 million, or 28%, to $365.4 million in 2004 from $285.4 million in 2003. Excluding the favorable impact of currency translation, net product sales in 2004 grew by approximately $69.6 million, or 24%, 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 $21.9 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 by Business Segment. Net product sales by business segment for 2004 and 2003 are as follows:

(in thousands)	2004 (restated)	2003 (restated)	% Increase
Consumer diagnostic products	$ 158,706	$ 127,056	25%
Vitamins and nutritional supplements	77,923	71,637	9%
Professional diagnostic products	128,803	86,737	49%
Total net product sales	$ 365,432	$ 285,430	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 $39.7 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 $0.8 million resulted from our organic growth, primarily due to increased sales of our rapid diagnostic tests for the point of care market.

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

(in thousands)	2004 (restated)	2003 (restated)	% Increase
United States	$ 218,251	$ 181,026	21%
Europe	98,136	69,594	41%
Other	49,045	34,810	41%
Total net product sales	$ 365,432	$ 285,430	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 and Royalty Revenue. License and royalty 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.

Gross Profit and Margin. Gross profit increased by $19.5 million, or 15%, to $147.0 million in 2004 from $127.5 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 $21.2 million, or 17%, comparing 2004 to 2003.

The gross profit increase of $21.2 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. The remaining increase of $1.3 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 and the commencement of our supply of the Pfizer e.p.t products, 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 39% 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 177 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 188 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 $20.7 million, or 17%, to $141.8 million in 2004 from $121.1 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/ (decrease)
Consumer diagnostic products	$ 82,909	$ 70,910	17%
Vitamins and nutritional supplements	8,775	14,577	(40)%
Professional diagnostic products	50,079	35,562	41%
Total gross profit from net product sales	$ 141,763	$ 121,049	17%

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 $14.5 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 39% 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).

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 $194.4 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 8.8% 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 $0.6 million, or 21%, to $2.3 million in 2004 from $2.9 million in 2003. The effective tax rate in 2004 was (16)%, compared to 25% 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 $16.6 million in 2004, while we generated net income of $8.7 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 $17.3 million, or $0.87 per basic and diluted common share, in 2004, compared to net income available to common stockholders of $7.7 million, or $0.49 and $0.44 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 12 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K for the calculation of net (loss) income 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, expected funding resulting from our co-development funding agreement with ITI Scotland and the proceeds from our February 2006 equity offering 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 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. We also expect to rely on our credit facilities and the capital markets to fund a portion of our capital needs and other commitments.

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 operations of Ischemia, Binax, BioStar, IDT and the Determine business 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, 2005, we had cash and cash equivalents of $34.3 million, a $17.5 million increase, or 105%, from December 31, 2004. 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 2005, we generated cash of $26.6 million from our operating activities, which resulted from a net loss of $19.2 million, adjusted for non-cash items of $36.0 million and a net working capital increase, excluding the change in cash balance and adjusted for acquired assets, of $9.8 million. The increase in adjusted working capital primarily resulted from an increase in our inventory and prepaid assets, offset by a decrease in accounts receivable. A net payment of $17.0 million from Quidel under an infringement litigation settlement is included in our net loss for 2005. Our non-equity financing activities, primarily borrowings under our primary senior credit facility, net of various debt repayments and financing costs, provided us with cash of $66.4 million during the year ended December 31, 2005. In addition, we received $97.4 million in net proceeds from an equity offering and the exercises of common stock options during the year ended December 31, 2005.

In 2005, we used cash of $170.8 million for investing activities which consisted of $149.0 million paid for transaction costs associated with previously acquired businesses and the 2005 acquisitions of ACS, Ischemia, Binax, the Determine business, BioStar and IDT. Additionally, we used cash to fund $20.0 million in capital expenditures, net of proceeds from sales of equipment and a $1.8 million increase in other non-current assets. Fluctuations in foreign currencies negatively impacted our cash balance by $2.1 million in 2005.

Investing Activities

During the year ended December 31, 2005, we incurred $20.0 million in capital expenditures, net of proceeds from sales of equipment. Significant capital expenditures during the year ended December 31, 2005 included: $1.9 million in connection with upgrading one of our vitamins and nutritional supplements plants and machinery; $0.9 million in connection with the transition of the manufacturing of the TestPack product, which we acquired as part of the rapid diagnostics business from Abbott, to our facilities, $2.0 million related to equipment in support of our research and development efforts at our facility in Stirling, Scotland, and $1.4 million in connection with our manufacturing facility in Bedford, England related to expansion of our production capabilities. The remaining capital expenditures during the fiscal year ended December 31, 2005 were incurred for the purchase of additional or replacement equipment to support our organic growth and various research and development activities and to furnish our new facility in China.

On January 24, 2005, we acquired the consumer pregnancy test business of ACS for an aggregate purchase price of $4.9 million which consisted of $4.6 million in cash and $0.3 million in estimated direct acquisition costs. 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 March 16, 2005, we acquired Ischemia, a privately held, venture-backed company that developed, manufactured and marketed the only FDA-cleared *in vitro* diagnostic test targeted on cardiac ischemia. The aggregate purchase price was $27.2 million, which consisted of 968,000 shares of our common stock with an aggregate fair value of $22.8 million, estimated exit costs of $1.5 million to vacate Ischemia's manufacturing and administrative facilities, estimated direct acquisition costs of $2.4 million and $0.5 million in assumed debt.

On March 31, 2005, we acquired Binax, a privately held developer, manufacturer and distributor of rapid diagnostic products for infectious disease testing, primarily related to the respiratory system. The aggregate purchase price was $44.7 million, which consisted of $9.0 million in cash, 1,422,000 shares of our common stock with an aggregate fair value of $35.2 million and $0.5 million in estimated direct

acquisition costs. The terms of the acquisition agreement also provide for $11.0 million of contingent cash consideration payable to the Binax shareholders upon the successful completion of certain new product developments during the five years following the acquisition.

On June 30, 2005, we acquired the Determine business. The Determine business produces diagnostic tests that are designed to provide rapid qualitative results for detecting several diseases, including hepatitis, HIV 1/2 and syphilis. The aggregate purchase price was $58.1 million, which consisted of $56.5 million in cash and $1.6 million in estimated direct acquisition costs.

On September 30, 2005, we acquired IDT, a Spanish distributor of diagnostic products. The aggregate purchase price was $20.3 million, which consisted of $11.7 million in cash, an $8.4 million working capital adjustment, which was paid during the fourth quarter of fiscal year 2005, and $0.2 million in estimated direct acquisition costs.

On September 30, 2005, we acquired BioStar, a leading developer and manufacturer of high-performance, rapid diagnostic tests, including tests for the detection of infectious diseases. The aggregate purchase price was $53.7 million, which consisted of $53.1 million in cash, $0.5 million in estimated direct acquisition costs and $0.1 million in estimated exit costs.

Financing Activities

On February 10, 2004, we completed the sale of $150.0 million of 8.75% senior subordinated notes, or bonds, due 2012 in a private placement to qualified institutional buyers. The proceeds from the bond issuance were used to repay certain of our then existing debt and provided us with additional funds for our operations. 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 are payable semi-annually in arrears on each February 15 and August 15, which commenced on August 15, 2004. As we were unable to consummate the exchange offer until March 28, 2005, 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. As of December 31, 2005, accrued interest related to the bonds amounted to $5.4 million.

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.

In August 2005, we sold 4,000,000 shares of common stock to funds affiliated with 3 accredited institutional investors in a private placement. Net proceeds from the private placement were approximately $92.8 million. Of this amount, we repaid principal and interest outstanding under our senior credit facility of $84.4 million, with the remainder of the net proceeds retained for general corporate purposes. $20.0 million of the repayment was used to permanently reduce the outstanding term loan balance under the senior credit facility.

On February 8 and 9, 2006, we sold 3,400,000 shares of our common stock at $24.41 per share to funds affiliated with 14 accredited institutional investors in a private placement. Proceeds from the private placement were approximately $79.3 million, net of issuance costs of $3.7 million. Of this amount, we repaid principal and interest outstanding under our senior credit facility of $74.1 million, with the remainder of the net proceeds retained for general corporate purposes.

On February 28, 2006, we acquired 67.45% of the capital stock of CLONDIAG chip technologies GmbH, a private company located in Jena in Germany which has developed a multiplexing technology for nucleic acid and immunoassay based diagnostics, in exchange for 218,502 shares of our common stock and approximately $3.1 million in cash. We also agreed to settle obligations totaling approximately $10.0 million during the first quarter of 2006, primarily using cash. Under our agreement with the CLONDIAG shareholders, we will acquire the remaining 32.55% of the capital stock of CLONDIAG on or about August 31, 2006 for an additional $4.9 million based on current exchange rates. The agreement also calls for contingent consideration totaling approximately $8.9 million consisting of 224,316 shares of common stock and approximately $3.0 million of cash or stock in the event that four specified products are developed on CLONDIAG's platform technology during the three years following the date of the initial stock purchase.

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 $100.0 million, subject to continuing covenant compliance. As of December 31, 2005, we had $89.0 million of outstanding borrowings under the revolving lines of credit. $73.6 million of the outstanding debt was used to fund the acquisitions of BioStar and IDT.

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 above certain thresholds.

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, 2005, the applicable interest rate under the revolving lines of credit, including the applicable margin, ranged from 6.84% to 9.25%.

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, as amended.

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 Laboratories. 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, 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 and the consent of our senior lenders. 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.

As of December 31, 2005, we had an aggregate of $1.7 million in outstanding capital lease obligations which are payable through 2009.

Income Taxes

As of December 31, 2005, we had approximately $170.2 million and $26.0 million of domestic and foreign net operating loss, or NOL, carryforwards, respectively, which either expire on various dates through 2025 or can be carried forward indefinitely. The NOL carryforward for CDIL is approximately $14.7 million. The CDIL NOL is fully reserved and may never be realized, due to the closing of the facility. 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, 2005 included approximately $71.2 million of pre-acquisition losses at IMN, Ischemia, Ostex and ADC. The future benefit of these losses will be applied first to reduce to zero any goodwill and other non-current intangible assets related to the acquisitions, prior to reducing our income tax expense. Also included in our domestic NOL carryforwards at December 31, 2005 was approximately $2.6 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, 2005.

Contractual Obligations

The following table summarizes our principal contractual obligations as of December 31, 2005 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**	**2006**	**2007-2008**	**2009-2010**	**Thereafter**
			(in thousands)		
Long-term debt obligations(1)	$ 261,528	$ 2,367	$ 109,161	$	$ 150,000
Capital lease obligations(2)	1,691	644	1,035	12	
Operating lease obligations(3)	56,926	7,551	10,913	8,069	30,393
Long-term and other liabilities(4)	7,471	2,886	2,492	1,436	657
Minimum royalty obligations	280	220	40	20	
Purchase obligations capital expenditure	4,952	4,952			
Purchase obligations other(5)	35,769	35,769			
Interest on debt(6)	85,711	15,150	29,728	26,250	14,583
Total	$ 454,328	$ 69,539	$ 153,369	$ 35,787	$ 195,633

(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 $1.5 million in technology license payment obligations and $6.0 million in pension obligations.

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

(6) Amounts are based on $150.0 million senior subordinated notes and $20.0 million subordinated promissory notes. Amounts exclude interest on all other debt due to variable interest rates (Note 6).

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, 2005 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 acquisitions of the rapid diagnostics business in September 2003 and the Determine business in June 2005 from Abbott, we entered into a transition services agreement with Abbott, whereby Abbott would continue to distribute certain of the acquired products for a period of up to 18 months following each acquisition. During the transition period, we recognized revenue on sales of the products when title transferred 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

Certain sales arrangements 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. When such analysis is not available and a right of return exists, we record revenue when the right of return is no longer applicable. 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 $51.2 million, $55.2 million and $46.2 million, or 13%, 15% and 16% of net product sales in 2005, 2004 and 2003, 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 $70.5 million and $61.3 million, net of allowances for doubtful accounts of $9.7 million and $9.4 million, as of December 31, 2005 and 2004, respectively.

Valuation of Inventories

We state our inventories at the lower of the actual cost to purchase or manufacture the inventory or the estimated current market value of the inventory. In addition, we periodically review the inventory quantities on hand and record a provision for excess and obsolete inventory. This provision reduces the carrying value of our inventory and is calculated based primarily upon factors such as forecasts of our customers' demands, shelf lives of our products in inventory, loss of customers and manufacturing lead times. Evaluating these factors, particularly forecasting our customers' demands, requires management to make assumptions and estimates. Actual product sales may prove our forecasts to be inaccurate, in which case we may have underestimated or overestimated the provision required for excess and obsolete inventory. If, in future periods, our inventory is determined to be overvalued, we would be required to recognize the excess value as a charge to our cost of sales at the time of such determination. Likewise, if, in future periods, our inventory is determined to be undervalued, we would have over-reported our cost of sales, or understated our earnings, at the time we recorded the excess and obsolete provision. Our inventory balance was $71.2 million and $61.2 million, net of a provision for excess and obsolete inventory of $7.7 million and $4.1 million, as of December 31, 2005 and 2004, 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, 2005, the balances of property, plant and equipment, goodwill and other intangible assets, net of accumulated depreciation and amortization, were $72.2 million, $322.2 million and $188.3 million, respectively.

Goodwill and other intangible assets are initially created as a result of business combinations or acquisitions of intellectual property. The values we record for goodwill and other intangible assets represent fair values calculated by 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 $85.7 million and $236.5 million, respectively, as of December 31, 2005. As of September 30, 2005, 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, 2005, 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, 2005, 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, 2005, 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 $96.7 million as of December 31, 2005 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. We did not repatriate any of our foreign earnings under this provision. 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 material 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 May 2005, the FASB issued SFAS No. 154, "*Accounting Changes and Error Corrections*," which replaces ABP Opinion No. 20, "*Accounting Changes*," and FASB Statement No. 3, "*Reporting Accounting Changes in Interim Financial Statements*," and changes the requirements for the accounting for and reporting of a change in accounting principle. SFAS No. 154 requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. SFAS No. 154 shall be effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. Early adoption is permitted for accounting changes and corrections of errors made in fiscal years beginning after the date SFAS No. 154 was issued. At the present time, we do not believe that adoption of SFAS No. 154 will have a material effect on our financial position, results of operations or cash flows.

In March 2005, the FASB issued FASB Interpretation No. 47, "*Accounting for Conditional Asset Retirement Obligations*," which is an interpretation of FASB Statement No. 143, "*Accounting for Asset Retirement Obligations.*" The interpretation requires a liability for the fair value of a conditional asset retirement obligation be recognized if the fair value of the liability can be reasonable estimated. The interpretation is effective for years ending after December 15, 2005. The interpretation is not expected to have a material impact on our results of operations or financial position.

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.

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. Under the original guidance of SFAS No. 123R, we were to adopt the statement's provisions for the interim period beginning after June 15, 2005. However, in April 2005, as a result of an action by the Securities and Exchange

Commission, companies were allowed to adopt the provisions of SFAS No. 123R at the beginning of their fiscal year that begins after June 15, 2005. Consequently, we adopted SFAS No. 123R on January 1, 2006. If we had adopted this standard in 2005, our net loss for 2005 would have been $6.2 million (or $0.25 per diluted share) higher than reported in 2005. While 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, the amount of the increase in operating expenses will depend on the level of future grants, the terms and fair values of such grants, and expected volatilities, among other factors, present at the grant dates. The adoption of SFAS No. 123R will have no impact on our cash flows.

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 material should be recognized as current period charges in all circumstances. Additionally, SFAS No. 151 requires that a facility's fixed production overhead be charged to inventory based on the normal capacity of the production facility. As required, we adopted 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.

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, 2005, our short-term investments approximated market value.

At December 31, 2005, we had revolving lines of credit available to us of up to $100.0 million in the aggregate under our primary senior credit facility, against which $89.0 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, 2005, the LIBOR and Index rates applicable under our primary senior credit facility were 4.37% and 7.25%, 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, 2005 over the next twelve months is quantified and summarized as follows:

(in thousands)	Interest Expense Increase
Interest rates increase by 1 basis point	$ 890
Interest rates increase by 2 basis points	$ 1,780

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 2005, the net impact of foreign currency changes on transactions was a loss of $0.3 million. Historically, we have not used derivative financial instruments or other financial instruments with original maturities in excess of three months to hedge such economic exposures. However, during 2005 we entered into forward exchange contracts totaling $24.9 million with monthly maturity dates of January 18, 2005 to February 15, 2006. Maturing forward exchange contracts were used to lock in U.S. dollar to British Pound Sterling (GBP) or U.S. dollar to Euro exchange rates and hedge anticipated intercompany sales. The change in value of the derivative was analyzed quarterly for changes in the spot and forward rates based on rates given by the issuing financial institution for each quarter end date. The effective portion of the gain or loss on the derivative is reported in other comprehensive income ("OCI") during the period prior to the forecasted purchase or sale. For forecasted sales on credit, the amount of income ascribed to each forecasted period was reclassified from OCI to income or expense on the date of the sale. The income or cost ascribed to each period encompassed within the periods of the recognized foreign-currency- denominated receivable or payable was reclassified from OCI to income or expense at the end of each reporting period. The changes in the derivative instrument's fair values from inception of the hedge were compared to the cumulative change in the hedged item's fair value attributable to the risk hedged. Effectiveness was based on the change in the spot rates. At December 31, 2005, we had two forward exchange contracts outstanding for $1.5 million each against the GBP. The contracts maturing during January and February 2006 effectively hedge existing receivables and therefore are considered fair value hedges and accordingly, as of December 31, 2005, the forward contracts remain effective against future exchange rate changes.

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 34.8% in 2005. If the U.S. dollar had been stronger by 1%, 5% or 10%, compared to the actual rates during 2005, our gross margin on total net product sales would have been 34.9%, 35.4% and 36.0%, 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 2005, the U.S. dollar was stronger by:		
1%	$ 1,277	$ 13
5%	$ 6,385	$ 63
10%	$ 12,770	$ 126

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.

As discussed on page 27 of Item 6. "Selected Consolidated Financial Data" and in Note 2(p) of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K, we have previously restated our consolidated financial statements as of and for the year ended December 31, 2004 and the quarters therein and for the quarter ended March 31, 2005 to correct errors under GAAP relating to the recognition of revenue. We determined that certain customers of one of our diagnostics divisions were provided return or exchange rights in connection with the sale of certain products for which reliable estimates of return or exchange had not been made, as a result of which the revenue associated with those sales should not have been recognized upon shipment to the customers under GAAP. As a result, we recorded $2.6 million in net revenue reversal with a $2.1 million gross profit and corresponding net loss impact spread over each of the quarters of 2004 and the first quarter of 2005.

The following presents selected unaudited quarterly financial data for each of the quarters in the years ended December 31, 2005 and 2004.

	2005			
	First Quarter(2)	Second Quarter(3)	Third Quarter(4)	Fourth Quarter(5)
	restated			
	(in thousands, except per share data)			
Net revenue	$ 91,920	$ 102,271	$ 106,294	$ 121,365
Gross profit	$ 32,189	$ 34,713	$ 39,635	$ 45,775
Net (loss) income	$ (7,802)	$ 2,503	$ (6,572)	$ (7,338)
Net (loss) income available to common stockholders basic and diluted(1)	$ (7,802)	$ 2,503	$ (6,572)	$ (7,338)
Net (loss) income per common share basic(1)	$ (0.37)	$ 0.11	$ (0.25)	$ (0.27)
Net (loss) income per common share diluted(1)	$ (0.37)	$ 0.11	$ (0.25)	$ (0.27)

	2004			
	First Quarter(6)	Second Quarter(7)	Third Quarter(8)	Fourth Quarter(9)
	restated	restated	restated	restated
Net revenue	$ 91,108	$ 89,143	$ 96,677	$ 97,063
Gross profit	$ 37,197	$ 35,328	$ 37,716	$ 36,763
Net loss	$ (3,383)	$ (6,733)	$ (2,880)	$ (3,600)
Net loss available to common stockholders basic and diluted(1)	$ (4,132)	$ (6,733)	$ (2,880)	$ (3,600)
Net loss per common share basic and diluted(1)	$ (0.22)	$ (0.34)	$ (0.14)	$ (0.18)

(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 12 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 2005 is a charge of $1.6 million associated with a recall of certain drugs of abuse products and an $8.4 million gain from a legal settlement in our nutritionals business.

(3) Included in net income in the second quarter of 2005 is a charge of $2.4 million associated with a reserve for excess quantities of certain raw materials and finished goods, a charge of $3.5 million associated with our decision to cease operations at our facility in Galway, Ireland, a charge of $4.2 million related to a legal settlement with PBM, and a $15.0 million gain related to an intellectual property settlement with Quidel relating to periods prior to 2005.

(4) Included in net loss in the third quarter of 2005 is a charge of $0.7 million associated with our decision to cease operations at our facility in Galway, Ireland.

(5) Included in net loss in the fourth quarter of 2005 is a charge of $0.9 million principally associated with our decision to cease operations at our facility in Galway, Ireland.

(6)

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.

(7)

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.

(8) 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.

(9) 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.

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

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 effectiveness of our company's internal control over financial reporting as of December 31, 2005. 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). Based on management's assessment and those criteria, management determined that the Company maintained effective internal control over financial reporting as of December 31, 2005.

In conducting management's evaluation of the effectiveness of our Company's internal control over financial reporting, management excluded the acquisitions of Binax, BioStar and IDT, which were completed in 2005. The contribution from these acquisitions represented approximately 3.8%, 1.6% and 0.9% of net revenues and 3.2%, 2.9% and 3.0% of total assets, respectively, as of and for the year ended December 31, 2005. Refer to Note 4 of the consolidated financial statements for further discussion of these acquisitions and other acquisitions and their impact on our consolidated financial statements.

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 effectiveness of our internal control over financial reporting as of December 31, 2005.

REPORT OF THE INDEPENDENT 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 maintained effective internal control over financial reporting as of December 31, 2005 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 Inverness Medical Innovations, Inc. and subsidiaries 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.

As indicated in the accompanying Management's Report on Internal Control Over Financial Reporting, management's assessment of and conclusion on the effectiveness of annual internal control over financial reporting did not include the internal controls of Binax, BioStar and IDT, which are included in the 2005 consolidated financial statements of Inverness Medical Innovations, Inc. and subsidiaries and constituted approximately 3.8%, 1.6%, and 0.9% of consolidated net revenues and 3.2%, 2.9%, and 3.0% of consolidated total assets, respectively, as of and for the year ended December 31, 2005. Management did not assess the effectiveness of internal control over financial reporting at these entities because Inverness Medical Innovations, Inc. and subsidiaries acquired these entities during 2005. Refer to Note 4 to the consolidated financial statements for further discussion of these acquisitions and their impact on Inverness Medical Innovations, Inc. and subsidiaries consolidated financial statements. Our audit of internal control over financial reporting of Inverness Medical Innovations, Inc. and subsidiaries also did not include an evaluation of the internal control over financial reporting of the entities referred to above.

In our opinion, management's assessment that Inverness Medical Innovations, Inc. and subsidiaries maintained effective internal control over financial reporting as of December 31, 2005, 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, Inverness Medical Innovations, Inc. and subsidiaries maintained effective internal control over financial reporting as of December 31, 2005, based on the criteria established in *Internal Control Integrated Framework* issued by the COSO.

We have also audited, in accordance with the standards of the Public Accounting Oversight Board (United States) the consolidated financial statements of Inverness Medical Innovations, Inc. and subsidiaries and our report therein dated March 14, 2006 expressed an unqualified opinion.

/s/ BDO Seidman, LLP

Boston, MA
March 14, 2006

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 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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 2006 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 AND RELATED STOCKHOLDER MATTERS

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. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(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 the notes, thereto, included here in.

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)
2.6	Asset Purchase Agreement, dated as of May 28, 2005 by and among Abbott Laboratories, Abbott Cardiovascular, Inc., Abbott Japan, Co., Ltd., Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH and Inverness Medical Japan, Ltd. (incorporated by reference to Exhibit 2.1 to the Company's Current Report of Form 8-K dated June 30, 2005)
*2.7	Stock Purchase Agreement, dated September 16, 2005, by and between Inverness Medical Innovations, Inc., Thermo Electron Corporation and Thermo Bioanalysis Corporation
2.8	Acquisition Agreement, dated February 24, 2006, by and among Inverness Medical Innovations, Inc., ACON Laboratories, Inc., AZURE Institute, Inc., LBI, Inc., Oakville Hong Kong Co., Ltd., ACON Biotech (Hangzhou) Co., Ltd. And Karsson Overseas Ltd. (incorporated by reference to Exhibit 99.1 to the Company's Current Report of Form 8-K dated February 24, 2006)
*2.9	Share Purchase Agreement, dated February 28, 2006, by and between Inverness Medical Switzerland Gmbh, Inverness Medical Innovations, Inc., CLONDIAG Beteiligungs-Gesellschaft GmbH, Eugen Ermantraut, Dr. Stefan Wölfl, Dr. Torsten Schulz, Prof. Dr. Albert Hinnen, Karl Fusseis, Prof. Dr. Michael Köhler and Thomas Ellinger
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	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)
4.2	First Supplemental Indenture, dated as of June 15, 2004, among Inverness Medical Innovations, Inc., the Guarantors, Advantage Diagnostics Corporation and U.S. Bank Trust National Association, as Trustee (incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2004)
4.3	Second Supplemental Indenture, dated as of October 20, 2004, among Inverness Medical Innovations, Inc., the Guarantors, IVC Industries, Inc. and U.S. Bank Trust National Association, as Trustee (incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2004)
4.4	Third Supplement Indenture, dated as of March 16, 2005, among Inverness Medical Innovations, Inc., the Guarantors, Ischemia Technologies, Inc. and U.S. Bank Trust National Association as Trustee (incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2005)
4.5	Fourth Supplement Indenture, dated as of March 31, 2005, among Inverness Medical Innovations, Inc., the Guarantors, Binax, Inc. and U.S. Bank Trust National Association, as Trustee (incorporated by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2005)
4.6	Fifth Supplemental Indenture, dated as of September 30, 2005, among Inverness Medical Innovations, Inc., the Guarantors, Thermo BioStar Inc. and U.S. Bank Trust National Association, as Trustee (incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q for the period ended September 30, 2005)
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	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)
10.3	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))
10.4	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))
10.5	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)
*10.6	Inverness Medical Innovations, Inc. 2001 Employee Stock Purchase Plan Second Amendment
10.7	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)
10.8	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)

10.9	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)
10.10	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)
10.11	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)
10.12	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)
10.13	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)
10.14	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)
10.15	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)
10.16	Lease between WE 10 Southgate LLC and Binax, Inc. dated as of August 26, 2004 (incorporated by reference to Exhibit 10.7 to the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2005)
+10.17	Research and Development Agreement, dated February 25, 2005, among ITI Scotland Limited and Inverness Medical Innovations, Inc., Stirling Medical Innovations Limited and Inverness Medical Switzerland GmbH (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q for the period ended March 31, 2005)
*10.18	Form of Stock Purchase Agreement, dated February 3, 2006, between the Company and the Investor named therein
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	Warrant for the Purchase of Shares of Common Stock of the Company, dated as of March 31, 2005, issued to Roger Piasio
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	Third Amended and Restated Credit Agreement, dated as of June 30, 2005 by and among Wampole Laboratories, LLC and Inverness Parties Signatory thereto, as Credit Parties, the Lenders Signatory thereto from time to time, as Lenders, General Electric Capital Corporation, as administrative agent, Merrill Lynch Capital, a division of Merrill Lynch Business Financial Services Inc., as documentation agent, a co-syndication agent and a co-lead arranger, UBS Securities LLC, as a co-syndication agent and GECC Capital Markets Group, Inc., as a co-lead arranger (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, event date June 30, 2005, filed on July 7, 2005)
10.33	First Amendment and Consent to Third Amended and Restated Credit Agreement, dated as of September 29, 2005, to the Third Amended and Restated Credit Agreement, dated as of June 30, 2005, by and among General Electric Capital Corporation, as Agent, Inverness Medical Innovations, Inc., Wampole Laboratories, LLC 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, a co-syndication agent and lender, UBS Securities LLC, as a co-syndication agent, and the lenders signatory thereto from time to time (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, event date September 29, 2005, filed on October 4, 2005)

10.34	Second Amendment to Third Amended and Restated Credit Agreement, dated as of November 8, 2005, to the Third Amended and Restated Credit Agreement, dated as of June 30, 2005, by and among General Electric Capital Corporation, as Agent, Inverness Medical Innovations, Inc., Wampole Laboratories, LLC 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, a co-syndication agent and lender, UBS Securities LLC, as a co-syndication agent, 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 September 30, 2005)
*10.35	Third Amendment to Third Amended and Restated Credit Agreement, dated as of November 22, 2005, to the Third Amended and Restated Credit Agreement, dated as of June 30, 2005, by and among General Electric Capital Corporation, as Agent, Inverness Medical Innovations, Inc., Wampole Laboratories, LLC 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, a co-syndication agent and lender, UBS Securities LLC, as co-syndication agent, and the lenders signatory thereto from time to time
*10.36	Fourth Amendment and Consent to Third Amended and Restated Credit Agreement, dated as of February 27, 2006, to the Third Amended and Restated Credit Agreement, dated as of June 30, 2005, by and among General Electric Capital Corporation, as Agent, Inverness Medical Innovations, Inc., Wampole Laboratories, LLC 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, a co-syndication agent and lender, UBS Securities LLC, as co-syndication agent, and the lenders signatory thereto from time to time
*10.37	Commercial lease, dated June 25, 2001, by and between Thermo BioStar, Inc. and The Park at CTC, LLC
*10.38	First Amendment to Lease, dated November __, 2002, between Thermo BioStar, Inc. and The Park at CTC, LLC.
10.39	Amendment No. 2 to Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 4.6 to Company's Registration Statement on Form S-8, as amended (File No. 333-106996))
10.40	Amendment No. 3 to Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.3 to Company's Quarterly Report on Form 10-Q, for the period ended June 30, 2005)
10.41	Rules of Inverness Medical Innovations, Inc. Inland Revenue Approved Option Plan (adopted as subplan to Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan) (incorporated by reference to Exhibit 10.2 to Company's Quarterly Report on Form 10-Q for the period ended June 30, 2005)
10.42	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.4 to Company's Quarterly Report on Form 10-Q for the period ended June 30, 2005)
10.43	Form of Non-Qualified Stock Option Agreement for Senior Executives under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.5 to Company's Quarterly Report on Form 10-Q for the period ended June 30, 2005)

10.44	Form of Incentive Stock Option Agreement for Senior Executives under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan (incorporated by reference to Exhibit 10.6 to Company's Quarterly Report on Form 10-Q for the period ended June 30, 2005)
+10.45	Manufacturing and Support Services Agreement, dated June 30, 2005, by and among Abbott Japan Co., Ltd., Abbott Laboratories, Inverness Medical Innovations, Inc., Inverness Medical Switzerland GmbH and Inverness Medical Japan, Ltd. (incorporated by reference to Exhibit 10.8 to Company's Quarterly Report on Form 10-Q for the period ended June 30, 2005)
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)
+10.50	Reagent Supply Agreement, dated June 30, 2005, by and between Abbott Laboratories, Inverness Medical Innovations, Inc. and Inverness Medical Japan, Ltd (incorporated by reference to Exhibit 10.9 to Company's Quarterly Report on Form 10-Q for the period ended June 30, 2005).
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, 2006
*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 15, 2006 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 15, 2006
/s/ CHRISTOPHER J. LINDOP Christopher J. Lindop	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 15, 2006
/s/ CAROL R. GOLDBERG Carol R. Goldberg	Director	March 15, 2006
/s/ ROBERT P. KHEDERIAN Robert P. Khederian	Director	March 15, 2006
/s/ JOHN F. LEVY John F. Levy	Director	March 15, 2006
/s/ JERRY MCALEER Jerry McAleer	Director	March 15, 2006
/s/ JOHN A. QUELCH John A. Quelch	Director	March 15, 2006
/s/ DAVID SCOTT David Scott	Director	March 15, 2006
/s/ PETER TOWNSEND Peter Townsend	Director	March 15, 2006
/s/ ALFRED M. ZEIEN	Director	March 15, 2006

Signature	Title	Date
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, 2005 and 2004, 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, 2005. 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 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 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, 2005 and 2004, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2005, in conformity with accounting principles generally accepted in the United States of America.

As discussed in Note 2(p) of the consolidated financial statements, the Company has previously restated its financial statements as of and for the years ended December 31, 2004 and 2003 to account properly for previously unidentified return or exchange rights in connection with the sale of certain products for which reliable estimates of return or exchange had not been made, as a result of which the revenue associated with those sales should not have been recognized upon shipment.

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, 2005, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). Our report dated March 14, 2006, expressed an unqualified opinion on management's assessment on the effectiveness of internal control over financial reporting and an unqualified opinion on the effectiveness of internal control over financial reporting.

/s/ BDO Seidman, LLP

Boston, Massachusetts
March 14, 2006

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

(in thousands, except per share amounts)

	2005	2004	2003
		(restated)	(restated)
Net product sales	$ 406,457	$ 365,432	$ 285,430
License and royalty revenue	15,393	8,559	9,728
Net revenue	421,850	373,991	295,158
Cost of sales	269,538	226,987	167,641
Gross profit	152,312	147,004	127,517
Operating expenses:			
Research and development	30,992	31,954	24,280
Sales and marketing	72,103	57,957	52,504
General and administrative	59,821	52,707	35,452
Stock-based compensation(1)	169		447
Total operating expenses	163,085	142,618	112,683
Operating (loss) income	(10,773)	4,386	14,834
Interest expense, including amortization of discounts and write-off of deferred financing costs (Note 6)	(21,795)	(22,114)	(9,711)
Other income, net	20,178	3,407	6,441
(Loss) income before income taxes	(12,390)	(14,321)	11,564
Provision for income taxes	6,819	2,275	2,911
Net (loss) income	$ (19,209)	$ (16,596)	$ 8,653
Net (loss) income available to common stockholders basic and diluted (Note 12)	$ (19,209)	$ (17,345)	$ 7,695
Net (loss) income per common share basic (Notes 2(k) and 12)	$ (0.79)	$ (0.87)	$ 0.49
Net (loss) income per common share diluted (Notes 2(k) and 12)	$ (0.79)	$ (0.87)	$ 0.44
Weighted average shares basic	24,358	19,969	15,711
Weighted average shares diluted	24,358	19,969	17,490

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

Research and development	$	$	$ 87

Sales and marketing			
General and administrative	169		360
Total stock-based compensation	$ 169	$	$ 447

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,	
	2005	**2004**
		(restated)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 34,270	$ 16,756
Accounts receivable, net of allowances of $9,748 and $9,359 at December 31, 2005 and 2004, respectively	70,476	61,347
Inventories	71,209	61,234
Deferred tax assets	844	2,819
Prepaid expenses and other current assets	17,534	9,601
Total current assets	194,333	151,757
Property, plant and equipment, net	72,211	66,780
Goodwill	322,210	221,155
Other intangible assets with indefinite lives	63,742	50,542
Core technology and patents, net	64,050	40,327
Other intangible assets, net	60,489	27,680
Deferred financing costs, net, and other non-current assets	13,469	9,156
Deferred tax assets	662	872
Total assets	$ 791,166	$ 568,269
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Current portion of long-term debt	$ 2,367	$ 88
Current portion of capital lease obligations	542	467
Accounts payable	42,155	32,345
Accrued expenses and other current liabilities	64,746	56,242
Total current liabilities	109,810	89,142
Long-term liabilities:		
Long-term debt, net of current portion	258,617	189,268
Capital lease obligations, net of current portion	978	1,401
Deferred tax liabilities	18,881	12,596
Other long-term liabilities	5,572	4,446
Total long-term liabilities	284,048	207,711
Commitments and contingencies (Notes 7, 8 and 10)		
Series A redeemable convertible preferred stock, $0.001 par value:		
Authorized: 2,667 shares		
Issued: 2,527 shares at December 31, 2005 and 2004		
Outstanding: none at December 31, 2005 and 2004		
Stockholders' equity:		

	December 31,	
Preferred stock, $0.001 par value		
Authorized: 2,333 shares		
Issued: none		
Common stock, $0.001 par value		
Authorized: 50,000 shares		
Issued and outstanding: 27,497 shares at December 31, 2005 and 20,711 shares at December 31, 2004	27	21
Additional paid-in capital	515,147	359,583
Notes receivable from stockholders	(14,691)	(14,691)
Accumulated deficit	(110,227)	(91,018)
Accumulated other comprehensive income	7,052	17,521
Total stockholders' equity	397,308	271,416
Total liabilities and stockholders' equity	$ 791,166	$ 568,269

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

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

	Common Stock								
	Number of Shares	$0.001 Par Value	Additional Paid-in Capital	Notes Receivable from Stockholders	Deferred Compensation	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' Equity	Comprehensive Income (Loss)
BALANCE, DECEMBER 31, 2002	14,907	$ 15	$ 251,458	$ (14,691)	$ (48)	$ (81,369)	$ 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 and shares issued under employee stock purchase plan	435	1	4,051					4,052	
Conversion of series A redeemable convertible preferred stock to common stock (Note 13(b))	230		3,824			(362)		3,462	
Dividends related to series A redeemable convertible preferred stock (Note 13(b))						(33)		(33)	
Redemption interest and amortization of beneficial conversion feature related to series A redeemable convertible preferred stock (Note 13(b))						(562)		(562)	
Fair value of assumed and fully-vested stock options and warrants related to acquisition of Ostex International, Inc. (Note 4(c))			1,752					1,752	
Stock-based compensation related to grants of common stock options			399					399	
Amortization of deferred compensation					48			48	
Other (Note 14)							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						8,653		8,653	8,653
Total comprehensive income									$ 13,982
BALANCE, DECEMBER 31, 2003	19,640	$ 20	$ 341,704	$ (14,691)	$	$ (73,673)	$ 11,813	$ 265,173	

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)	(restated)
BALANCE, DECEMBER 31, 2003	19,640	$ 20	$ 341,704	$ (14,691)	$ (73,673)	$ 11,813	$ 265,173	
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 and shares issued under employee stock purchase plan	153		1,998				1,998	
Conversion of series A redeemable convertible preferred stock to common stock (Note 13(b))	416	1	6,933		(739)		6,195	
Redemption interest related to series A redeemable convertible preferred stock (Note 13(b))					(10)		(10)	
Conversion of convertible subordinated promissory notes to common stock (Note 6(d))	346		6,034				6,034	
Other (Note 14)						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					(16,596)		(16,596)	(16,596)
Total comprehensive loss								$ (10,888)
BALANCE, DECEMBER 31, 2004	20,711	$ 21	$ 359,583	$ (14,691)	$ (91,018)	$ 17,521	$ 271,416	

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)	(restated)
BALANCE, DECEMBER 31, 2004	20,711	$ 21	$ 359,583	$ (14,691)	$ (91,018)	$ 17,521	$ 271,416	
Issuance of common stock in connection with acquisitions and equity offering, net of issuance costs of $2,481	6,391	6	150,210				150,216	
Exercise of common stock options and warrants and shares issued under employee stock purchase plan	395		5,185				5,185	
Stock-based compensation related to grants of common stock options			169				169	
Changes in cumulative translation adjustment						(10,300)	(10,300)	$ (10,300)
Reclassification of gain related to sale of available for sale securities						(169)	(169)	(169)
Net loss					(19,209)		(19,209)	(19,209)
Total comprehensive loss								$ (29,678)
BALANCE, DECEMBER 31, 2005	27,497	$ 27	$ 515,147	$ (14,691)	$ (110,227)	$ 7,052	$ 397,308	

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)

	2005	2004	2003
		(restated)	(restated)
Cash Flows from Operating Activities:			
Net (loss) income	$ (19,209)	$ (16,596)	$ 8,653
Adjustments to reconcile net (loss) income to net cash provided by operating activities:			
Interest expense related to amortization of non-cash original issue discount, non-cash beneficial conversion feature and deferred financing costs	2,345	4,929	1,565
Non-cash loss (income) related to currency hedge and interest rate swap agreements	217	(695)	(528)
Non-cash stock-based compensation expense	169		447
Non-cash value on settlement of litigation	(2,593)	(495)	
Impairment of long-lived assets	1,740		
Loss on sale of fixed assets	263		
Depreciation and amortization	27,756	23,500	16,435
Deferred income taxes	5,969	2,232	812
Other non-cash items	141	(36)	
Changes in assets and liabilities, net of acquisitions:			
Accounts receivable, net	10,404	(4,095)	(9,592)
Inventories	(4,047)	(11,073)	(2,584)
Prepaid expenses and other current assets	(7,598)	2,116	(4,102)
Accounts payable	6,201	(6,897)	6,715
Accrued expenses and other current liabilities	4,496	15,049	(8,020)
Other non-current liabilities	339	356	
Net cash provided by operating activities	26,593	8,295	9,801
Cash Flows from Investing Activities:			
Purchases of property, plant and equipment	(20,233)	(20,389)	(11,135)
Proceeds from sale of property, plant and equipment	241	385	152
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	(141)	(1,415)	(1,903)
Cash paid for purchase of the Wampole Division of MedPointe Inc.			(1,460)
Cash paid for purchase of IVC Industries, Inc., net of cash acquired	(63)	(256)	(535)
Cash paid for purchase of Unipath business, net of cash acquired		(50)	(649)
Cash paid for purchase of Advanced Clinical Systems Pty Ltd	(4,971)		
Cash paid for purchase of Ischemia Technologies, Inc., net of cash acquired	(4,096)		
Cash paid for purchase of Binax, Inc., net of cash acquired	(7,972)		
Cash paid for purchase of the Determine business	(58,102)		
Cash paid for purchase of Thermo BioStar, Inc.	(53,607)		
Cash paid for purchase of Innogenetics Diagnostica Y Terapeutica, S.A.U, net of cash acquired	(20,030)		
Cash paid for purchase of other businesses and intellectual property		(8,524)	(4,007)
(Increase) decrease in other assets	(1,787)	(1,889)	396
Net cash used in investing activities	(170,761)	(34,302)	(89,130)
Cash Flows from Financing Activities:			
Cash paid for financing costs	(2,873)	(5,671)	(4,533)
Proceeds from issuance of common stock, net of issuance costs	97,440	1,905	4,003
Net (repayment) proceeds under revolving line of credit	69,442	(30,830)	19,331
Proceeds from issuance of senior subordinated notes		150,000	
Proceeds from borrowings under notes payable	269		57,621
Repayments of notes payable		(97,830)	(5,785)
Principal payments of capital lease obligations	(501)	(477)	(651)
Net cash provided by financing activities	163,777	17,097	69,986

	2005	2004	2003
Foreign exchange effect on cash and cash equivalents	(2,095)	1,044	3,297
Net increase (decrease) in cash and cash equivalents	17,514	(7,866)	(6,046)
Cash and cash equivalents, beginning of year	16,756	24,622	30,668
Cash and cash equivalents, end of year	$ 34,270	$ 16,756	$ 24,622

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)

	2005	2004 (restated)	2003 (restated)
Supplemental Disclosure of Cash Flow Information:			
Interest paid	$ 19,268	$ 13,535	$ 9,091
Taxes paid	$ 4,106	$ 3,067	$ 1,447
Supplemental Disclosure of Non-cash Activities:			
On September 30, 2005, we acquired Thermo BioStar, Inc. (Note 4 (a))			
Accounts receivable	$ 5,247	$	$
Inventories	2,046		
Property, plant and equipment	1,510		
Other assets	795		
Intangible assets	49,083		
Accrued exit costs	(83)		
Accounts payable and accrued expenses	(4,991)		
Cash paid for purchase of Thermo BioStar, Inc.	(53,607)		
	$	$	$
On September 30, 2005, we acquired Innogenetics Diagnostica Y Terapeutica, S.A.U. (Note 4 (a))			
Accounts receivable	$ 10,913	$	$
Inventories	520		
Property, plant and equipment	771		
Other assets	188		
Intangible assets	12,062		
Accrued acquisition costs	(210)		
Accounts payable and accrued expenses	(3,164)		
Deferred tax liability	(1,050)		
Cash paid for purchase of Innogenetics Diagnostica Y Terapeutica, S.A.U., net of acquired cash	(20,030)		
	$	$	$
On June 30, 2005, we acquired the Determine business from Abbott Laboratories (Note 4 (a))			
Inventories	$ 3,412	$	$
Property, plant and equipment	1,500		
Intangible assets	56,913		
Accrued expenses	(3,723)		
Cash paid for purchase of the Determine business	(58,102)		
	$	$	$
On March 31, 2005, we acquired Binax, Inc. (Note 4 (a))			
Accounts receivable	$ 5,264	$	$

	2005	2004	2003
Inventories	3,086		
Property, plant and equipment	2,421		
Other assets	688		
Intangible assets	35,596		
Accounts payable and accrued expenses	(2,076)		
Deferred tax liability, net	(1,794)		
Cash paid for purchase of Binax, Inc., net of cash acquired	(7,972)		
Fair value of common stock issued	$ 35,213	$	$

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)

	2005	2004	2003
		(restated)	(restated)
On March 16, 2005, we acquired Ischemia Technologies, Inc. (Note 4 (a))			
Accounts receivable	$ 58	$	$
Inventories	40		
Property, plant and equipment	288		
Intangible assets	26,932		
Other assets	99		
Assumed liabilities	(50)		
Accrued acquisition costs	(144)		
Accounts payable and accrued expenses	(377)		
Cash paid for purchase of Ischemia Technologies, Inc., net of cash acquired	(4,096)		
Fair value of common stock issued	$ 22,750	$	$
On September 30, 2003, we acquired certain assets from Abbott Laboratories (Note 4 (c))			
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(c))			
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	141	1,177	(2,086)
Cash paid for purchase of Ostex International, Inc., net of cash acquired	(141)	(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

	2005	2004	2003
On September 20, 2002, we acquired the Wampole Division from MedPointe Inc.			
Accounts receivable	$	$	$ (451)
Inventories			(75)
Other current assets			1
Property and equipment			156
Intangible assets			1,138
Accounts payable and accrued expenses			(201)
Accrued acquisition costs			892
Cash paid for purchase of the Wampole Division from MedPointe Inc.			(1,460)
	$	$	$

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)

	2005	2004 (restated)	2003 (restated)
On March 19, 2002, we acquired IVC Industries, Inc.			
Accounts receivable	$	$	$
Inventories			
Property and equipment			
Other assets			
Accounts payable and accrued expenses			
Other accrued acquisition costs	63	256	535
Long-term debt			
Cash paid for purchase of IVC Industries, Inc., net of cash acquired	(63)	(256)	(535)
	$	$	$
During 2005, 2004 and 2003, we acquired other businesses and intellectual property			
Accounts receivable	$	$ 471	$ 116
Inventories		914	
Property, plant and equipment		173	616
Intangible assets	4,971	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	(4,971)	(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 12 and 13(b))	$	$ 749	$ 958
Conversion of preferred stock to common stock (Note 13(b))	$	$ 6,934	$ 3,824
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 2005, we acquired Thermo BioStar, Inc. ("BioStar") on September 30, 2005, Innogenetics Diagnostica Y Terapeutica, S.A.U. ("IDT") on September 30, 2005, the Determine/DainaScreen assets of Abbott Laboratories' rapid diagnostic business (the "Determine business") on June 30, 2005, Binax, Inc. ("Binax") on March 31, 2005, Ischemia Technologies, Inc. ("Ischemia") on March 16, 2005 and the consumer pregnancy test business of Advanced Clinical Systems Pty Ltd ("ACS") on January 24, 2005 (Note 4 (a)). BioStar develops and manufactures high-performance, rapid diagnostic tests, including tests for the detection of infectious diseases. IDT is a Spanish distributor of diagnostic products. The Determine business produces diagnostic tests that are designed to provide rapid qualitative results for detecting several diseases, including hepatitis, HIV 1/2 and syphilis. Binax is a developer, manufacturer and distributor of rapid diagnostic products for infectious disease testing, primarily related to the respiratory system. Ischemia was a privately held, venture-backed company that developed, manufactured and marketed the only FDA-cleared *in vitro* diagnostic test targeted on cardiac ischemia. In acquiring ACS, we obtained the rights to the Crystal Clear brand, the leading consumer pregnancy test in Australia, and a leading position in New Zealand.

During 2004, we acquired Advantage Diagnostics Corporation ("ADC") on June 16, 2004 and Viva Diagnostika ("Viva") on June 2, 2004 (Note 4(b)). 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 (c)). The business acquired from Abbott in 2003 relates 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 ApS ("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 in consolidation. 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 losses of $0.3 million and $0.7 million during 2005 and 2004, respectively, and gain of $5,000 during 2003, 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, 2005 and 2004.

(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 is 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 $14.9 million, $13.1 million and $10.1 million in 2005, 2004 and 2003, respectively. Expenditures for repairs and maintenance are expensed as incurred.

(f) Goodwill and Other Intangible Assets

We review the valuation of goodwill in accordance with SFAS No. 142, *Goodwill and Other Intangible Assets*. Under the provisions of SFAS No. 142, goodwill is required to be tested for impairment annually, in lieu of being amortized, using a fair value approach at the reporting unit level. Furthermore, goodwill is required to be tested for impairment on an interim basis if an event or circumstance indicates that it is more likely than not an impairment loss has been incurred. An impairment loss shall be recognized to the extent that the carrying amount of goodwill exceeds its implied fair value. Impairment losses shall be recognized in operations. Our valuation methodology for assessing impairment requires management to make judgments and assumptions based on historical experience and projections of future operating performance. If these assumptions differ materially from future results, we may record impairment charges in the future. Our annual impairment review performed on September 30, 2005 did not indicate that goodwill related to our consumer diagnostic products or to our professional diagnostic products reporting units was impaired.

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

We examine, in accordance with SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*, 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. We believe that the carrying values of our other long-lived tangible and intangible assets were realizable as of December 31, 2005.

(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 15).

(i) Revenue Recognition

The majority of our revenues is 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. Certain sale arrangements require us to accept product returns. When a right of return exists, we record revenue when the right of return is no longer applicable. In connection with the acquisitions of the rapid diagnostic business in September 2003 (Note 4 (c)) and the Determine business in June 2005 (Note 4(a)) from Abbott, we entered into a transition services agreement with Abbott, whereby Abbott would continue to distribute certain of the acquired products sold for a period of up to 18 months following each acquisition. During the transition period, we recognized revenue on sales of the products when title transferred 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 13(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:

	2005	2004 (restated)	2003 (restated)
	(in thousands, except per share amounts)		
Net (loss) income as reported	$ (19,209)	$ (16,596)	$ 8,653
Stock-based employee compensation as reported(a)	139		397
Pro forma stock-based employee compensation	(6,366)	(5,675)	(6,161)
Net (loss) income pro forma	$ (25,436)	$ (22,271)	$ 2,889
Net (loss) income per common share basic			
Net (loss) income as reported	$ (0.79)	$ (0.87)	$ 0.49
Stock-based employee compensation as reported	0.01		0.02
Pro forma stock-based employee compensation	(0.26)	(0.28)	(0.39)
Net (loss) income per share pro forma	$ (1.04)	$ (1.15)	$ 0.12
Net (loss) income per common share diluted			
Net (loss) income as reported	$ (0.79)	$ (0.87)	$ 0.44
Stock-based employee compensation as reported	0.01		0.02
Pro forma stock-based employee compensation	(0.26)	(0.28)	(0.35)
Net (loss) income per share pro forma	$ (1.04)	$ (1.15)	$ 0.11

(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, 2005 were as follows:

	2005	2004	2003
Risk-free interest rate	3.58-4.46%	2.80-3.95%	2.33-3.49%
Expected dividend yield			
Expected lives	5 years	5 years	5 years
Expected volatility	45%	47%	55%

The weighted average fair value under the Black-Scholes option pricing model of options granted to employees during 2005, 2004 and 2003 was $11.85, $9.86 and $9.34, 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") at the beginning of the fiscal year that begins after June 15, 2005. Consequently, we adopted SFAS No. 123R on January 1, 2006. See Note 2(o) for further discussion.

(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 12).

(l) Other Operating Expenses

We expense advertising costs as incurred. In 2005, 2004 and 2003, advertising costs amounted to $21.7 million, $19.9 million and $18.6 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, 2005 and 2004 that were in excess of 10% of the gross accounts receivable balance on those dates. During 2005, 2004 and 2003, we had one customer that represented 10%, 11% and 11%, respectively, of our net revenues, who purchases both our consumer diagnostic products and vitamins and nutritional supplements.

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.

(n) Financial Instruments and Fair Value of Financial Instruments

Our primary financial instruments at December 31, 2005 and 2004 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, 2005 and 2004. 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. 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*. At December 31, 2005, we had outstanding foreign currency exchange forward contracts totaling $3.0 million. Changes of $217,000 in the market value of these contracts during 2005 were recorded to other income, net in our consolidated statements of operations.

(o) Recent Accounting Pronouncements

In May 2005, the FASB issued SFAS No. 154, "*Accounting Changes and Error Corrections*," which replaces ABP Opinion No. 20, "*Accounting Changes*," and FASB Statement No. 3, "*Reporting Accounting Changes in Interim Financial Statements*," and changes the requirements for the accounting for and reporting of a change in accounting principle. SFAS No. 154 requires retrospective application to prior periods' financial statements of changes in accounting principle, unless it is impracticable to determine either the period-specific effects or the cumulative effect of the change. SFAS No. 154 shall be effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005. Early adoption is permitted for accounting changes and corrections of errors made in fiscal years beginning after the date SFAS No. 154 was issued. We do not believe that adoption of SFAS No. 154 will have a material effect on our financial position, results of operations or cash flows.

In March 2005, the FASB issued FASB Interpretation No. 47, "*Accounting for Conditional Asset Retirement Obligations*," which is an interpretation of FASB Statement No. 143, "*Accounting for Asset Retirement Obligations.*" The interpretation requires a liability for the fair value of a conditional asset retirement obligation be recognized if the fair value of the liability can be reasonable estimated. The interpretation is effective for years ending after December 15, 2005. The interpretation is not expected to have a material impact on our results of operations or financial position.

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.

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. Under the original guidance of SFAS No. 123R, we were to adopt the statement's provisions for the interim period beginning after June 15, 2005. However, in April 2005, as a result of an action by the Securities and Exchange Commission, companies were allowed to adopt the provisions of SFAS No. 123R at the beginning of their fiscal year that begins after June 15, 2005. Consequently, we adopted SFAS No. 123R on January 1, 2006. If we had adopted this standard in 2005, our net loss for 2005 would have been $6.2 million (or $0.25 per diluted share) higher than reported in 2005. While 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, the amount of the increase in operating expenses will depend on the level of future grants, the terms and fair values of such grants, and expected volatilities, among other factors, present at the grant dates. The adoption of SFAS No. 123R will have no impact on our cash flows.

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 material should be recognized as current period charges in all circumstances. Additionally, SFAS No. 151 requires that a facility's fixed production overhead be charged to inventory based on the normal capacity of the production facility. As required, we adopted 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.

(p) Restatements of 2004 and 2003 Financial Statements

We previously restated our consolidated financial statements as of and for the years ended December 31, 2004 and 2003 and for the quarter ended March 31, 2005 to correct errors under GAAP relating to the recognition of revenue. During 2005, we determined that certain customers of one of our diagnostics divisions were provided return or exchange rights in connection with the sale of products, as a result of which the revenue associated with those sales should not have been recognized upon shipment to the customers under GAAP. As a result, we recorded $4.5 million in net revenue reversal with a $3.4 million gross margin and corresponding net loss impact spread over the quarters of 2004 and 2003 and an increase in both revenues and gross profit of $0.3 million in the first quarter of 2005. The restatements as a result of the errors relating to the recognition of revenue are reflected in the amounts below as "as restated on August 26, 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 reported amounts included in our 2004 Annual Report on Form 10-K, filed with the SEC on March 16, 2005 ("as reported") and the effect of such restatements on net (loss) income and net (loss) income per share.

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

	2004	
	As restated on August 26, 2005	As reported
	(in thousands, except per share amounts)	
Net product sales	$ 365,432	$ 368,351
Cost of sales	226,987	227,548
Net loss	(16,596)	(14,238)
Net loss per common share basic and diluted	$ (0.87)	$ (0.75)

	December 31, 2004	
	As restated on August 26, 2005	As reported
	(in thousands)	
Inventories	$ 61,234	$ 60,145
Accrued expenses and other current liabilities	$ 56,242	$ 51,886
Accumulated deficit	$ (91,018)	$ (87,752)

	2003	
	As restated on August 26, 2005	As reported
	(in thousands, except per share amounts)	
Net product sales	$ 285,430	$ 286,984
Cost of sales	$ 167,641	$ 168,171
Provision for income taxes	$ 2,911	$ 3,028
Net income	$ 8,653	$ 9,560
Net income per common share basic	$ 0.49	$ 0.55
Net income per common share diluted	$ 0.44	$ 0.49

	December 31, 2003	
	As restated on August 26, 2005	As reported
	(in thousands)	
Inventories	$ 47,953	$ 47,423
Accrued expenses and other current liabilities	$ 42,559	$ 41,122
Accumulated deficit	$ (73,672)	$ (72,765)

(3) Other Balance Sheet Information

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

	December 31,	
	2005	2004
		(restated)
	(in thousands)	
Inventories:		
Raw materials	$ 25,488	$ 23,434
Work-in-process	17,812	14,956
Finished goods	27,909	22,844
	$ 71,209	$ 61,234
Property, plant and equipment, net:		
Machinery, laboratory equipment and tooling	$ 78,559	$ 67,650
Land and buildings	8,942	9,053
Leasehold improvements	18,980	12,037
Computer software and equipment	8,811	7,358
Furniture and fixtures	3,982	2,992
	119,274	99,090
Less: Accumulated depreciation and amortization	(47,063)	(32,310)
	$ 72,211	$ 66,780
Accrued expenses and other current liabilities:		
Compensation and compensation-related	$ 8,959	$ 11,121
Advertising and marketing	6,608	9,036
Professional fees	5,649	5,615
Interest payable	6,002	5,631
Royalty obligations	4,001	5,342
Deferred revenue	5,981	4,473
Other	27,546	15,024
	$ 64,746	$ 56,242

(4) Business Combinations

All of the acquisitions discussed below, with the exception of the acquisition of the consumer pregnancy test business of ACS (Note 4(a)) and of Biomar Diagnostic Systems GmbH ("Biomar") (Note 4(b)), 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) Acquisitions in 2005

(i)

Acquisition of BioStar

On September 30, 2005, we acquired BioStar, a leading developer and manufacturer of high-performance, rapid diagnostic tests, including tests for the detection of infectious diseases. The aggregate purchase price was $53.7 million, which consisted of $53.1 million in cash, $0.5 million in estimated direct acquisition costs and $0.1 million in estimated exit costs, which we recorded in accordance with Emerging Issues Task Force ("EITF") No. 95-3, *Recognition of Liabilities in Connection with a Purchase Business Combination*.

The following is a summary of the allocation of the aggregate purchase price to the assets acquired and the liabilities assumed at the date of the acquisition:

		(in thousands)
Accounts receivable	$	5,247
Inventories		2,046
Property, plant and equipment		1,510
Goodwill		30,843
Core technology		4,550
Customer relationships		6,760
OIA trade name		2,730
Trademarks		4,200
Other assets		795
Accounts payable and accrued expenses		(4,991)
Total consideration	$	53,690

The acquisition of BioStar is accounted for as a purchase under SFAS No. 141, *Business Combinations*. Accordingly, the operating results of BioStar have been included in our consolidated financial statements of operations after the acquisition date as part of our professional diagnostic products reporting unit. We have assigned indefinite lives to the acquired goodwill and certain trademarks. The value of such goodwill is fully deductible for tax purposes over 15 years. The values allocated to the acquired core technology, customer relationships and OIA trade names are being amortized on a straight-line basis over their estimated useful lives of 10, 5 and 10 years, respectively. The weighted average amortization period for the acquired intangible assets with finite lives is 6.8 years. The trademarks, core technology, customer relationships and OIA trade name 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 sheet at December 31, 2005.

(ii)

Acquisition of IDT

On September 30, 2005, we acquired IDT, a Spanish distributor of diagnostic products. The aggregate purchase price was $20.3 million, which consisted of $11.7 million in cash, an $8.4 million working capital adjustment, which was paid during the fourth quarter of fiscal year 2005, and $0.2 million in estimated direct acquisition costs.

The following is a summary of the allocation of the aggregate purchase price to the assets acquired and the liabilities assumed at the date of the acquisition:

	(in thousands)
Cash and cash equivalents	$ 76
Accounts receivable	10,913
Inventories	520
Property, plant and equipment	771
Goodwill	9,062
Customer relationships	3,000
Other assets	188
Accounts payable and accrued expenses	(3,164)
Deferred tax liability	(1,050)
Total consideration	$ 20,316

The above values for the assets acquired and subsequent amortization and liabilities assumed are based on preliminary management estimates. Final purchase price allocation may differ from the above. Management is also in the process of determining the useful lives of the customer relationships as listed above. The estimated value allocated to the acquired customer relationships is being amortized on a straight-line basis over their estimated useful lives of 5 years. The customer relationships are included in other intangible assets, net, on the accompanying consolidated balance sheets.

The acquisition of IDT is accounted for as a purchase under SFAS No. 141. Accordingly, the operating results of IDT have been included in our consolidated financial statements of operations after the acquisition date as part of our professional diagnostic products reporting unit. Goodwill resulting from this acquisition is deductible for tax purposes.

(iii)

Acquisition of Determine business

On June 30, 2005, we acquired the Determine business which produces diagnostic tests that are designed to provide rapid qualitative results for detecting several diseases, including hepatitis, HIV 1/2 and syphilis. The aggregate purchase price was $58.1 million, which consisted of $56.5 million in cash and $1.6 million in estimated direct acquisition costs.

The following is a summary of the allocation of the aggregate purchase price to the assets acquired and liabilities assumed at the date of the acquisition:

	(in thousands)
Inventories	$ 3,412
Property, plant and equipment	1,500
Goodwill	40,913
Trademark	5,000
Customer relationships	7,500
Manufacturing know-how	3,500
Accrued expenses	(3,723)
Total consideration	$ 58,102

The above values for the assets acquired are based on preliminary management estimates due to the timing of the acquisition. Final purchase price allocation may differ from the above. Management is also in the process of determining the useful lives of the acquired intangibles as listed above. We have assigned indefinite lives to the acquired goodwill and trademark. Goodwill resulting from this acquisition is deductible for tax purposes over lives varying from 10 to 25 years, depending on the tax jurisdiction. We estimate the useful lives of the manufacturing know-how to be ten years and the customer relationships asset to be six years and 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 6.9 years.

The acquisition of the Determine business is accounted for as a purchase under SFAS No. 141. Accordingly, the operating results of the Determine business have been included in our consolidated statements of operations after the acquisition date as part of our professional diagnostic products reporting unit.

(iv)

Acquisition of Binax

On March 31, 2005, we acquired Binax, a privately held developer, manufacturer and distributor of rapid diagnostic products for infectious disease testing, primarily related to the respiratory system. The aggregate purchase price was $44.7 million, which consisted of $9.0 million in cash, 1.4 million shares of our common stock with an aggregate fair value of $35.2 million and $0.5 million in estimated direct acquisition costs. 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 acquisition agreement, pursuant to EITF No. 99-12, *Determination of the Measurement Date for the Market Price of Acquirer Securities Issued in a Purchase Business Combination.* The terms of the acquisition agreement also provide for $11.0 million of contingent cash consideration payable to the Binax shareholders upon the successful completion of certain new product developments during the five years following the acquisition. This contingent consideration will be accounted for as an increase in the aggregate purchase price if and when the contingency occurs.

The following is a summary of the allocation of the aggregate purchase price to the assets acquired and the liabilities assumed at the date of the acquisition:

	(in thousands)
Cash and cash equivalents	$ 1,556
Accounts receivable	5,264
Inventories	3,086
Property, plant and equipment	2,421
Goodwill	15,466
Product technology	3,900
Customer relationships	11,700
Trademark	4,500
Non-compete agreement	30
Other assets	688
Deferred tax asset	6,312
Accounts payable and accrued expenses	(2,076)
Deferred tax liability	(8,106)
	$ 44,741

We have assigned indefinite lives to the acquired goodwill and trademarks. Goodwill generated from this acquisition is not deductible for tax purposes. We estimate the useful lives of the product technology, customer relationships and the non-compete agreement to be 7, 13 and 7 years and have 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 10.7 years.

The acquisition of Binax is accounted for as a purchase under SFAS No. 141. Accordingly, the operating results of Binax have been included in our consolidated statement of operations since the acquisition date as part of our professional diagnostic products reporting unit.

(v)

Acquisition of Ischemia

On March 16, 2005, we acquired Ischemia, a privately held, venture-backed company that has developed, manufactures and markets the only FDA-cleared *in vitro* diagnostic test targeted on cardiac ischemia. The aggregate purchase price was $27.2 million, which consisted of 968,000 shares of our common stock with an aggregate fair value of $22.8 million, estimated exit costs of $1.5 million to vacate Ischemia's manufacturing and administrative facilities, which we recorded in accordance with EITF No. 95-3, estimated direct acquisition costs of $2.4 million and $0.5 million in assumed debt. The fair value of our common stock was determined in accordance with EITF No. 99-12.

The following is a summary of the allocation of the aggregate purchase price to the assets acquired and the liabilities assumed at the date of the acquisition:

	(in thousands)
Cash and cash equivalents	$ 115
Accounts receivable	58
Inventories	40
Property, plant and equipment	288
Goodwill	7,532
Patents	19,200
Customer relationships	200
Other assets	99
Deferred tax asset	7,760
Accounts payable and accrued expenses	(377)
Deferred tax liability	(7,760)
	$ 27,155

We have assigned indefinite lives to the acquired goodwill. Goodwill generated from this acquisition is not deductible for tax purposes. We estimated the useful lives of the patents to be from 9 to 15 years and customer related intangible asset to be 11 years and included them in core technology and patents, net, and other intangible assets, net, respectively, in the accompanying consolidated balance sheets.

The acquisition of Ischemia is accounted for as a purchase under SFAS No. 141. Accordingly, the operating results of Ischemia have been included in our consolidated statements of operations after the acquisition date as part of our professional diagnostic products reporting unit.

(vi)

Acquisition of ACS

On January 24, 2005, we acquired the consumer pregnancy test business of ACS. 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. The purchase price of ACS consisted of $4.6 million in cash and estimated direct acquisition costs of $0.3 million. The majority of the purchase price of ACS is allocated to the intangible asset, trademarks, with an average useful life of 7 years.

The acquisition of ACS is accounted for as a purchase under SFAS No. 141. Accordingly, the operating results for this business have been included in our consolidated statements of operations after the acquisition date as part of our consumer diagnostic product reporting unit.

(b) Acquisitions in 2004

(i)

Acquisition of Biomar

On December 10, 2004, our subsidiary, Inverness Medical Switzerland GmbH ("IMS"), settled a patent infringement lawsuit in Germany against 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 trade name, in exchange for a release of all past infringement claims. We accounted for this settlement in accordance with EITF 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.

The acquisition of Biomar is accounted for as a purchase under SFAS No. 141. Accordingly, the operating results of Biomar have been included in our consolidated statements of operations after the acquisition date as part of our professional diagnostic products reporting unit.

(ii)

Acquisition of ADC

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, as amended, 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 June 30, 2006. The payment of the contingent consideration, if any, will be recorded as an addition to the purchase price.

The acquisition of ADC is accounted for as a purchase under SFAS No. 141. Accordingly, the operating results of ADC have been included in our consolidated statements of operations after the acquisition date as part of our professional diagnostic products reporting unit.

(iii)

Acquisition of Viva

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 acquisition of Viva is accounted for as a purchase under SFAS No. 141. Accordingly, the operating results of Viva have been included in our consolidated statements of operations after the acquisition date as part of our professional diagnostic products reporting unit.

(c) Acquisitions in 2003

(i)

Acquisition of SMB

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 fair value of our common stock was determined in accordance with EITF No. 99-12.

The acquisition of the SMB is accounted for as a purchase under SFAS No. 141. Accordingly, the operating activities of SMB, which consist principally of research and development activities, have been included in our consolidated statements of operations after the acquisition date.

(ii)

Acquisition of 2003 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. 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. The fair value of our common stock was determined in accordance with EITF No. 99-12. 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 with varying lives of 15 to 25 years, depending on the tax jurisdiction, 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.

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.

(iii) Acquisition of ABI

On August 27, 2003, we acquired ABI from Apogent Technologies, Inc. ("Apogent"). 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 in accordance with EITF No. 99-12. 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 our consolidated statement of operations after 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.

(iv)

Acquisition of Ostex

On June 30, 2003, we acquired Ostex through a merger transaction. 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 19(b)) in accordance with EITF No. 95-3, 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 relationships		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 our consolidated statement of operations after the acquisition date as part of our professional diagnostic products reporting unit. Goodwill generated from this acquisition is not deductible for tax purposes. We estimated the useful lives of both the core technology

and customer relationships to be 15 years and have 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.

(d) Recent and Pending Acquisitions

On February 28, 2006, we acquired 67.45% of the capital stock of CLONDIAG chip technologies GmbH ("CLONDIAG"), a privately held company located in Jena in Germany, which has developed a multiplexing technology for nucleic acid and immunoassay based diagnostics, in exchange for 218,502 shares of our common stock and approximately $3.1 million in cash. We also agreed to settle obligations totaling approximately $10.0 million during the first quarter of 2006, primarily using cash. Under our agreement with the CLONDIAG shareholders, we will acquire the remaining 32.55% of the capital stock of CLONDIAG on or about August 31, 2006 for an additional $4.9 million based on current exchange rates. The agreement also calls for contingent consideration totaling approximately $8.9 million consisting of 224,316 shares of our common stock and approximately $3.0 million of cash or stock in the event that four specified products are developed on CLONDIAG's platform technology during the three years following the date of the initial stock purchase.

On February 24, 2006, we entered into a definitive agreement with ACON Laboratories, Inc. ("ACON") and certain of its affliliated entities to acquire (i) the assets of ACON's business of researching, developing, manufacturing, marketing and selling lateral flow immunoassay products in the United States, Canada, Europe (excluding Russia, the former Soviet Republics that are not part of the European Union and Turkey), Israel, Australia, Japan and New Zealand and (ii) all of the capital stock of entities owning a newly-constructed manufacturing facility currently undergoing validation in Hangzhou, China.

The aggregate purchase price for the acquired business, including the manufacturing facility, will be between $140.0 million and $175.0 million based upon a multiple of revenues and pre-tax profits of the acquired business, though we have agreed to acquire up to $4.0 million in indebtedness related to the new manufacturing facility. The aggregate purchase price is expected to be based on completion of certain milestones related to achievement of functional manufacturing operations in certain territories. Such purchase price shall be paid by issuing an aggregate of up to $50.0 million of our common stock, but in no event more than 2,130,000 shares, with the remainder of the purchase price being paid in cash.

The transaction is subject to the consent of our lenders and other ordinary and customary closing conditions, including certain regulatory approvals. The acquisition of the lateral flow business described above is expected to close in the first or second quarter of 2006 and the acquisition of the manufacturing facility is expected to close by the end of the second quarter of 2006.

(e) Pro Forma Financial Information

The following table presents selected unaudited financial information of our company, including ADC, Viva, Ischemia, Binax, the Determine business, BioStar and IDT, as if the acquisitions of these businesses had occurred on January 1, 2004. Pro forma results exclude adjustments for ACS as the historical results of this acquisition do not materially affect our results of operations. The pro forma results are derived from the historical financial results of the acquired businesses for all periods

presented and are not necessarily indicative of the results that would have occurred had the acquisitions been consummated on January 1, 2004.

	2005	2004
	(unaudited)	
	(in thousands, except per share amounts)	
Pro forma net revenues	$ 477,239	$ 464,285
Pro forma net loss	(18,387)	(20,949)
Pro forma net loss available to common stockholders basic and diluted	(18,387)	(21,698)
Pro forma net loss per common share basic and diluted(1)	$ (0.67)	$ (0.83)

(1) Net loss per share amounts are computed as described in Note 12.

(5) Goodwill and Other Intangible Assets

The following is a summary of goodwill and other intangible assets as of December 31, 2005:

	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value	Useful Life
		(in thousands)		
Amortized intangible assets:				
Core technology and patents	$ 79,163	$ 15,113	$ 64,050	1-20 years
Other intangible assets:				
Supplier relationships	11,020	3,616	7,404	10 years
Trademarks and trade names	17,414	6,335	11,079	5-25 years
License agreements	9,967	5,297	4,670	5-8.5 years
Customer relationships	38,100	7,196	30,904	1.5-15 years
Manufacturing know-how	7,000	720	6,280	10-15 years
Other	490	338	152	2-7 years
Total Other intangible assets	83,991	23,502	60,489	
Total intangible assets with finite lives	$ 163,154	$ 38,615	$ 124,539	
Intangible assets with indefinite lives:				
Goodwill	$ 322,210	$	$ 322,210	
Other intangible assets	63,742		63,742	
Total intangible assets with indefinite lives	$ 385,952	$	$ 385,952	

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

	Gross Carrying Amount	Accumulated Amortization	Net Carrying Value	Useful Life
		(in thousands)		
Amortized intangible assets:				
Core technology and patents	$ 50,347	$ 10,020	$ 40,327	1-20 years
Other intangible assets:				
Supplier relationships	11,020	2,512	8,508	10 years
Trademarks and trade names	9,978	5,133	4,845	5-25 years
License agreements	9,747	3,912	5,835	7-8.5 years
Customer related intangible assets	9,191	4,277	4,914	1.5-15 years
Manufacturing know-how	3,500	311	3,189	15 years
Other	530	141	389	2-3 years
Total Other intangible assets	43,966	16,286	27,680	
Total intangible assets with finite lives	$ 94,313	$ 26,306	$ 68,007	
Intangible assets with indefinite lives:				
Goodwill	$ 221,155	$	$ 221,155	
Other intangible assets	50,542		50,542	
Total intangible assets with indefinite lives	$ 271,697	$	$ 271,697	

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 the straight-line method is appropriate, as it approximates the pattern in which economic benefits are consumed in circumstances where such patterns can be reliably determined. Amortization expense of intangible assets, which in the aggregate amounted to $12.9 million, $10.4 million and $6.3 million in 2005, 2004 and 2003, 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, 2005:

	(in thousands)
2006	$ 15,455
2007	$ 15,316
2008	$ 15,027
2009	$ 13,369
2010	$ 12,821

In accordance with SFAS No. 142, we perform annual impairment tests of the carrying value of our goodwill by reporting unit. Our annual impairment review on September 30, 2005, did not indicate that goodwill related to our consumer diagnostic products and professional diagnostic products

reporting units were impaired. The values assigned to the trade names that were acquired as part of our acquisition have been assigned indefinite lives and therefore, in accordance with SFAS No. 142 are not being amortized.

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

	Consumer Diagnostic Products	Professional Diagnostic Products	Total
		(in thousands)	
Goodwill, at December 31, 2003	$ 86,676	$ 130,057	$ 216,733
Acquisitions (Note 4 (b))		4,858	4,858
Other(1)	(598)	162	(436)
Goodwill, at December 31, 2004	86,078	135,077	221,155
Acquisitions (Note 4 (a))		103,815	103,815
Other(1)	(904)	(1,857)	(2,760)
Goodwill, at December 31, 2005	$ 85,174	$ 237,035	$ 322,210

(1) These amounts relate primarily to adjustments resulting from fluctuations in foreign currency exchange rates.

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. As of December 31, 2005, we had approximately $2.0 million of costs capitalized in connection with establishing patents and trademarks which 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.

(6) Long-term Debt

We had the following long-term debt balances outstanding:

	December 31,	
	2005	2004
	(in thousands)	
Senior credit facilities	$ 89,000	$ 20,053
8.75% Senior Subordinated notes	150,000	150,000
10% Subordinated notes	20,000	20,000
Line of credit	2,212	
Other	316	47
	261,528	190,100
Less: Unamortized original issue discount	(544)	(744)
Less: Current portion	(2,367)	(88)
	$ 258,617	$ 189,268

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. During 2003, to finance the cash portions of our acquisitions of ABI and the Abbott business (Note 4(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 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*. We retained the $50.0 million availability under the revolving lines of credit, subject to continued covenant compliance.

On June 30, 2005, we amended and restated our existing senior credit facility. The amendment expanded our existing revolving credit facility capacity from $50.0 million to $80.0 million and added a $20.0 million term loan facility. Upon completion of the amendment, we borrowed $58.0 million to finance our acquisition of the Determine business. In August, 2005, we sold 4.0 million shares of our common stock to three accredited institutional investors in a private placement. Net proceeds from the private placement were approximately $92.8 million. Of this amount, we repaid principal and interest outstanding under senior credit facility of $84.4 million, with the remainder of the net proceeds retained for general corporate purposes. $20.0 million of the repayment was used to permanently reduce the outstanding term loan balance under the senior credit facility. The repayment of the term

loan balance resulted in a non-cash write-off of deferred financing costs of $0.1 million during the third quarter of 2005. On September 29, 2005, we again amended the senior credit facility to increase the total amount of credit available to us under the senior credit facility, which consists of two revolving lines of credit, from $80.0 million to $100.0 million. As of December 31, 2005, $89.0 million of borrowings were outstanding under the lines, with $11.0 million available for future borrowings, subject to continued covenant compliance.

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 or (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, 2005, the interest rate under the revolving lines of credit, including the applicable margin, ranged from 6.84% to 9.25%. We recorded interest expense, including amortization of deferred financing costs, under these senior credit facilities in the aggregate amount of $2.3 million, $2.0 million and $4.6 million in 2005, 2004 and 2003, respectively. As of December 31, 2005, accrued interest related to the senior credit facility amounted to $0.5 million.

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, 2005, 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 are payable semi-annually in arrears on each February 15 and

August 15, which commenced 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 consummate the exchange offer until March 28, 2005, interest on the bonds increased by 0.25% point per year for the first 90-day period immediately following the default (from November 7, 2004 to February 4, 2005) and an additional 0.25% point per year until March 28, 2005. As of December 31, 2005, accrued interest related to the bonds amounted to $4.9 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 20 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. 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. As of December 31, 2005, accrued interest related to the 10% Subordinated Notes amounted to $0.5 million. All warrants issued in relation to this debt have been classified in equity, pursuant to the provisions of EITF 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*.

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, 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 and $1.0 million in 2004 and 2003, 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% Convertible 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% Convertible 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 and $0.8 million in 2004 and 2003, 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 20).

(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. 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) Maturities of Long-term Debt

The following is a summary of the maturities of long-term debt outstanding on December 31, 2005:

	(in thousands)
2006	$ 2,367
2007	143
2008	109,018
2009	
2010	
Thereafter	150,000
	261,528
Less: Unamortized original issue discount	(544)
	$ 260,984

(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. In July 2005, the facility and the related capital lease were transferred to another subsidiary of ours, IMI Nutritionals. The aggregate monthly minimum payments remaining under this capital lease are $1.5 million as of December 31, 2005. 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 $0.2 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, 2005:

	(in thousands)
2006	$ 644
2007	643
2008	392
2009	12
2010	
Total future minimum lease payments	1,691
Less: Imputed interest	(171)
Present value of future minimum lease payments	1,520
Less: Current portion	(542)
	$ 978

At December 31, 2005, 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	$ 198
Buildings	2,186
	2,384
Less: Accumulated amortization	(1,322)
	$ 1,062

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 $0.5 million, $0.4 million and $0.3 million in 2005, 2004 and 2003, 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.

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 2005 and 2004:

	2005	2004
	(in thousands)	
Change in projected benefit obligation		
Benefit obligation at beginning of year	$ 11,646	$ 5,003
Service cost		1,712
Interest cost	583	183
Plan participants' contributions		577
Plan amendments		4,926
Actuarial (gain) loss	258	(1,315)
Benefits paid	(122)	(128)
Foreign exchange impact	(1,221)	688
Benefit obligation at end of year	$ 11,144	$ 11,646
Change in accumulated benefit obligation		
Benefit obligation at beginning of year	$ 8,304	$ 5,003
Service cost		1,712
Interest cost	583	183
Plan participants' contributions		577
Plan amendments		1,740
Actuarial (gain) loss	258	(1,315)
Benefits paid	(122)	(128)
Foreign exchange impact	(882)	532
Benefit obligation at end of year	$ 8,141	$ 8,304
Change in plan assets		
Fair value of plan assets at beginning of year	$ 5,327	$ 1,964
Actual return on plan assets	1,316	73
Employer contribution	546	2,536
Plan participants' contributions		577
Benefits paid	(122)	(128)
Foreign exchange impact	(631)	305
Fair value of plan assets at end of year	$ 6,436	$ 5,327
Funded status	$ (4,708)	$ (6,319)
Unrecognized net actuarial (gain) loss	(1,414)	(780)
Unrecognized prior service cost	5,967	6,642
Net amount recognized	$ (155)	$ (457)

The net amount recognized in the accompanying consolidated balance sheet that relates to the Defined Benefit Plan during 2005 and 2004 consists of:

	2005	2004
	(in thousands)	
Accrued benefit liability	$ (1,672)	$ (3,085)
Accumulated other comprehensive income		
Intangible asset	1,517	2,628
Net amount recognized	$ (155)	$ (457)

The measurement date used to determine plan assets and benefit obligations for the Defined Benefit Plan was December 31, 2005 and 2004.

The following table provides the weighted-average actuarial assumptions:

	2005	2004
Assumptions used to determine benefit obligations:		
Discount rate	4.80%	5.30%
Rate of compensation increase	3.55%	3.55%
Assumptions used to determine net periodic benefit cost:		
Discount rate	5.30%	5.50%
Expected return on plan assets	6.84%	6.00%
Rate of compensation increase	3.55%	4.25%

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:

	2005	2004
	(in thousands)	
Service cost	$	$ 1,712
Interest cost	583	183
Expected return on plan assets	(360)	(183)
Recognition of prior service cost		1,099
Amortization of net loss	54	24
Net periodic benefit cost	$ 277	$ 2,835

The plan assets of the Defined Benefit Plan comprise of a mix of stocks and fixed income securities and other investments. At December 31, 2005, these stocks and fixed income securities represented 70% and 30%, respectively, of the market value of the pension assets. We expect to contribute approximately 0.3 million British Pounds Sterling (or $0.5 million at December 31, 2005) to the Defined Benefit Plan in 2006. 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 $0.2 million to be paid annually for the five years thereafter.

Unipath contributed $1.1 million, $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 2005, 2004 and 2003, respectively.

(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, 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.

During 2005, we entered into forward exchange contracts totaling $24.9 million with monthly maturity dates of January 18, 2005 to February 15, 2006. Maturing forward exchange contracts were used to lock in U.S. dollar to British Pound Sterling (GBP) or U.S. dollar to Euro exchange rates and hedge anticipated intercompany sales.

The change in value of the derivative was analyzed quarterly for changes in the spot and forward rates based on rates given by the issuing financial institution for each quarter end date. The effective portion of the gain or loss on the derivative is reported in other comprehensive income ("OCI") during the period prior to the forecasted purchase or sale. For forecasted sales on credit, the amount of income ascribed to each forecasted period was reclassified from OCI to income or expense on the date of the sale. The income or cost ascribed to each period encompassed within the periods of the recognized foreign-currency-denominated receivable or payable was reclassified from OCI to income or expense at the end of each reporting period. The changes in the derivative instrument's fair values from inception of the hedge were compared to the cumulative change in the hedged item's fair value attributable to the risk hedged. Effectiveness was based on the change in the spot rates.

At December 31, 2005, we had two forward exchange contracts outstanding for $1.5 million each against the GBP. The contracts maturing during January and February 2006 effectively hedge existing receivables and therefore are considered fair value hedges and accordingly, as of December 31, 2005, the forward contracts remain effective against future exchange rate changes.

(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 2021. The following schedule outlines future minimum annual rental payments under these leases at December 31, 2005:

	(in thousands)
2006	$ 7,551
2007	6,140
2008	4,773
2009	4,281
2010	3,788
Thereafter	30,393
	$ 56,926

Rent expense relating to operating leases was approximately $10.0 million, $7.4 million and $5.8 million during 2005, 2004 and 2003, 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 $2.6 million to $2.7 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, 2005, we had total outstanding non-cancelable equipment purchase commitments of $5.0 million.

(c) Legal Proceedings

We currently are not a party to any material pending legal 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. These suits can be expensive and result in counterclaims challenging the validity of our patents and other rights.

In addition, in December 2005 we learned that the Enforcement Division of the Securities and Exchange Commission (SEC) had issued a formal order of investigation in connection with the previously disclosed revenue recognition matter at one of our diagnostic divisions, and we subsequently received a subpoena for documents. We believe that we fully responded to the subpoena and we will continue to fully cooperate with the SEC's investigation. We cannot predict whether the SEC will seek additional information or what the outcome of its investigation will be.

On February 2, 2005, our IMN subsidiary received $8.4 million representing its pro rata share of the net funds which were disbursed 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. The $8.4 million is included in other income, net, in the accompanying consolidated statement of operations for the year ended December 31, 2005.

On April 6, 2005, we entered into a binding settlement agreement of our pending litigation with Princeton BioMeditech Corporation ("PBM") pursuant to which we paid $2.5 million in resolution of all pending litigation with PBM. PBM also received an option to permanently settle certain claims against our ABI subsidiary, that are not part of any pending case in exchange for $1.8 million of collaborative research and development funding from us. In connection with this settlement arrangement, we recorded a $4.2 million charge which is included in other income, net, in the accompanying consolidated statement of operations for the year ended December 31, 2005.

On April 27, 2005, we entered into a settlement agreement with Quidel Corporation ("Quidel") terminating all domestic and international intellectual property litigation with them. Under the settlement agreement, we received a net payment of $17.0 million and net future royalties from Quidel at 8.5%, in exchange for a license to all of our current and future patents which embody lateral flow technology for all diagnostic products other than for cardiology testing and for consumer/over-the-counter women's health (except that diagnostics for women's infectious diseases are within the licensed field of use). Quidel and its affiliates have granted a net royalty free cross-license of their current and future patents that embody lateral flow technology to us and all of our affiliates for all applications. The payment of $17.0 million is included in our financial results for the year ended December 31, 2005, of which $15.0 million related to periods prior to 2005 and has been included in other income, net, and the remainder has been recorded as license revenues.

On June 16, 2005, we entered into a license arrangement with British BioCell International Limited ("British BioCell"). As part of this agreement, we licensed to them our lateral flow intellectual property for use in certain defined areas not competitive with existing businesses in return for royalties on future sales totaling between 10% and 25% of net revenues, depending on the amounts of revenue earned. As part of the arrangement, we also received an option to acquire 25% of British BioCell's parent company, BBI Holdings, PLC, a UK public company. We valued the option at $2.6 million using the Black-Scholes option pricing model and have included the value received in other income, net, for the year ended December 31, 2005. The investment, which is not readily convertible to cash, has been

recorded at cost and will be evaluated at least annually for impairment, or more frequently, if events and circumstances indicate.

On September 23, 2005, an arbitrator issued a final award against our IMN subsidiary in favor of Sunlight Distribution, Inc. for damages in the amount of $1.8 million plus interest, fees and costs arising out of a distribution arrangement dated September 1996. We have accrued $2.9 million as of December 31, 2005 to provide for the final award. The corresponding expenses were recorded in other income, net, for the year ended December 31, 2005.

(11) Other Arrangements

(a) Co-development Agreement with ITI Scotland Limited

On February 25, 2005, we entered into a co-development agreement with ITI Scotland Limited ("ITI"), whereby ITI agreed to provide us with approximately 30 million British Pounds Sterling (or $51.8 million at December 31, 2005) 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 ("the programs"). We agreed to invest 37.5 million British Pounds Sterling (or $64.7 million at December 31, 2005) in the programs over the next three years. Through our subsidiary, Stirling Medical Innovations Limited ("Stirling"), we established 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. ITI and Stirling will have exclusive rights to the developed technology in their respective fields of use. As of December 31, 2005, we had received approximately $22.5 million in funding from ITI. As qualified expenditures are made under the co-development arrangement, we recognize the fee earned during the period as a reduction of our related expenses, subject to certain limitations. For the fiscal year ended December 31, 2005, we recognized $18.1 million of reimbursements, of which $17.2 million offset our research and development spending and $0.9 million reduced our general, administrative and marketing spending incurred by Stirling. Funds received from ITI in excess of amounts earned are included in accrued expenses and other current liabilities, the balance of which was $4.4 million as of December 31, 2005.

(b) 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. We consolidate 100% of this entity.

(12) (Loss) Income per Share

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

	2005	2004 (restated)	2003 (restated)
	(in thousands, except per share amounts)		
Numerator:			
Net (loss) income	$ (19,209)	$ (16,596)	$ 8,653
Dividends, redemption interest and amortization of beneficial conversion feature related to Series A Preferred Stock (Note 13(b))		(749)	(958)
Net (loss) income available to common stockholders basic and diluted	$ (19,209)	$ (17,345)	$ 7,695
Denominator:			
Denominator for basic (loss) income per share weighted average shares	24,358	19,969	15,711
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	24,358	19,969	17,490
Net (loss) income per share basic	$ (0.79)	$ (0.87)	$ 0.49
Net (loss) income per share diluted	$ (0.79)	$ (0.87)	$ 0.44

We had the following potential dilutive securities outstanding on December 31, 2005: (a) options and warrants to purchase an aggregate of 4.7 million shares of our common stock at a weighted average exercise price of $18.44 per share and (b) 104,000 shares of common stock held in escrow. Potential dilutive securities were not included in the computation of diluted loss per share in 2005 because the inclusion thereof would be antidilutive.

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.

(13) Stockholders' Equity

(a) Common Stock

As of December 31, 2005, we had 50.0 million shares of common stock, $0.001 par value, authorized, of which approximately 27.5 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 0.8 million shares were reserved for issuance upon exercise of outstanding warrants.

On August 1, 2005, we sold 4.0 million shares of our common stock at $23.76 per share to funds affiliated with three accredited institutional investors in a private placement. Proceeds from the private placement were approximately $92.8 million, net of issuance costs of $2.5 million. Of this amount, we repaid principal and interest outstanding under our senior credit facility of $84.4 million, with the remainder of the net proceeds retained for general corporate purposes.

On February 8 and 9, 2006, we sold 3.4 million shares of our common stock at $24.41 per share to funds affiliated with 14 accredited institutional investors in a private placement. Proceeds from the private placement were approximately $79.3 million, net of issuance costs of $3.7 million. Of this amount, we repaid principal and interest outstanding under our senior credit facility of $74.1 million, with the remainder of the net proceeds retained for general corporate purposes.

In connection with the February 2006 private placements of common stock, we agreed to use commercially reasonable efforts to register the private placement shares prior to June 8, 2006. In the event that we are unable to take a registration statement effective prior to June 8, 2006, we will pay an illiquidity discount equal to 1% of the February 2006 offering proceeds per month until the earlier of (i) the date that the registration statement is declared effective or (ii) February 8, 2008.

(b) Preferred Stock

As of December 31, 2005, 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 were outstanding as of December 31, 2005.

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 during 2003, which reduced earnings available to common stockholders in the computation of earnings per share (Note 12). 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 2005, 2004 and 2003, we amortized $0, $0.7 million and $0.5 million, respectively, of such discount, of which $0, $0.7 million, and $0.4 million, respectively, represented acceleration of amortization due to conversions of Series A Preferred Stock.

Had the Series A Preferred Stock not been converted to common stock, 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 $0, $10,000, and $0.4 million in 2005, 2004 and 2003, respectively, which reduced earnings available to common stockholders in the computation of earnings per share (Note 12).

(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 6.1 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, 2005, there were 0.4 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, 2005, 2004 and 2003. 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. 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, 2005, 2004 and 2003, 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, we recognized stock-based compensation expense related to certain of the IMT employees who

became our employees in the amount of $2,000, as such employees terminated their employment with us. No such stock-based compensation charge was recognized in 2005 and 2004.

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

	2005		2004		2003	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
	(in thousands)		(in thousands)		(in thousands)	
Outstanding at January 1	3,619	$ 16.58	3,398	$ 15.85	2,754	$ 14.84
Granted	809	$ 26.67	394	21.75	1,090	$ 18.71
Exercised	(331)	$ 11.94	(90)	10.40	(271)	$ 11.49
Forfeited	(195)	$ 21.48	(83)	18.12	(175)	$ 24.62
Outstanding at December 31	3,902	$ 18.82	3,619	$ 16.58	3,398	$ 15.85
Exercisable at December 31	2,424	$ 16.19	2,141	$ 15.06	1,591	$ 14.10

The following represents additional information related to stock options outstanding and exercisable at December 31, 2005:

	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)	(in years)		(in thousands)	
$1.25-$13.65	409	4.70	$ 6.64	346	$ 5.89
$14.58-$14.92	125	5.12	$ 14.89	125	$ 14.89
$15.35-$15.47	734	5.97	$ 15.46	726	$ 15.47
$15.55-$16.20	413	7.19	$ 16.05	230	$ 15.98
$16.46-$18.73	505	6.19	$ 17.58	457	$ 17.60
$19.55-$21.00	415	6.81	$ 20.66	253	$ 20.81
$21.15-$24.20	433	8.06	$ 22.74	205	$ 22.46
$24.25-$28.02	396	9.01	$ 24.94	68	$ 24.87
$28.03-$28.22	458	9.48	$ 28.09		$
$29.41-$165.96	14	3.07	$ 59.10	14	$ 59.10
$1.25-$165.96	3,902	7.00	$ 18.82	2,424	$ 16.19

(d) Warrants

The following is a summary of all warrant activity during the three years ended December 31, 2005:

	Number of Shares	Exercise Price	Weighted Average Exercise Price
	(in thousands)		
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
Granted	75	$ 24.00	$ 24.00
Exercised	(7)	$ 5.50-$13.54	$ 13.47
Forfeited	(9)	$ 14.15-$23.76	$ 18.66
Warrants outstanding and exercisable, December 31, 2005	758	$ 3.81-$24.00	$ 16.47

The following represents additional information related to warrants outstanding and exercisable at December 31, 2005:

	Outstanding and Exercisable		
Exercise Price	Number of Shares	Weighted Average Remaining Contract Life	Weighted Average Exercise Price
	(in thousands)	(in years)	
$3.81-$5.57	10	4.54	$ 4.77
$7.37-$10.90	42	6.77	$ 10.73
$13.54-$18.12	631	3.14	$ 16.14
$24.00	75	9.25	$ 24.00
	758	3.97	$ 16.47

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 0.5 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, 2005. The value of warrants

issued in connection with debt financings has yielded original issue discounts and additional interest expense of $0.2 million for both 2005 and 2004. All outstanding warrants have been classified in equity, pursuant to the provisions of EITF No. 00-19.

(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, 2005, 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 were 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 attained certain targeted prices per share. Performance determinations were made at the end of each calendar year, starting with December 31, 2002 and ending with December 31, 2005. No performance targets were achieved as of December 31, 2005, the date on which this plan expired.

(14) 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, 2005 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, 2002	$ 6,484	$	$	$ 6,484
Period change	5,627	(434)	136	5,329
Balance at December 31, 2003	12,111	(434)	136	11,813
Period change	5,241	434	33	5,708
Balance at December 31, 2004	17,352		169	17,521
Period change	(10,300)		(169)	(10,469)
Balance at December 31, 2005	$ 7,052	$	$	$ 7,052

(i) The $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. These securities were sold during fiscal year 2005.

(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.

(15) Income Taxes

Our income tax provision in 2005, 2004 and 2003 mainly represents those recorded by us and certain of our U.S. subsidiaries and by our foreign subsidiaries Unipath Limited in the United Kingdom, Inverness Medical Eurasia in Ireland, Inverness Medical Japan in Japan, and Inverness Medical Switzerland GmbH in Switzerland. (Loss) income before income taxes consists of the following:

	2005	2004	2003
		(restated)	(restated)
		(in thousands)	
United States	$ (40,582)	$ (20,102)	$ (817)
Foreign	28,192	5,781	$ 12,381
	$ (12,390)	$ (14,321)	$ 11,564

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,	
	2005	2004
		(restated)
	(in thousands)	
Deferred tax assets:		
NOL and capital loss carryforwards	$ 71,926	$ 46,758
Tax credit carryforwards	833	833
Nondeductible reserves	8,721	8,179
Nondeductible accruals	10,199	10,312
Difference between book and tax bases of tangible assets	932	212
Difference between book and tax bases of intangible assets	5,616	19,004
Gross deferred tax asset	98,227	85,298
Less: Valuation allowance	(96,721)	(81,607)
Total deferred tax assets	1,506	3,691
Deferred tax liabilities:		
Difference between book and tax bases of tangible assets	2,171	2,382
Difference between book and tax bases of intangible assets	16,710	10,214
Total deferred tax liability	18,881	12,596
Net deferred tax liability	$ 17,375	$ 8,905

As of December 31, 2005, we had approximately $170.2 million of domestic NOL carryforwards and $26 million of foreign NOL and foreign capital loss carryforwards, which either expire on various dates through 2025 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. Approximately $14.7 million of our foreign NOLs relate to CDIL. As a result of our closure of operations at CDIL, this NOL which is fully reserved at December 31, 2005, may never be realized. The domestic NOL carryforwards include approximately $71.2 million of pre-acquisition losses at IMN, Ischemia, 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 non-current intangible assets related to the acquisitions. Any remaining benefits would be recognized as a reduction of income tax expense. As

of December 31, 2005, $17.1 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 non-current intangible assets related to the acquisitions, prior to reducing our income tax expense. Included in the valuation allowance is approximately $2.6 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 $41.4 million at December 31, 2005. 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. We did 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:

	2005	2004 (restated)	2003 (restated)
		(in thousands)	
Current:			
State	$ 256	$ 404	$ 302
Foreign	575	(365)	1,465
	831	39	1,767
Deferred:			
Federal	2,650	2,341	1,687
State	247	209	172
Foreign	3,091	(314)	(715)
	5,988	2,236	1,144
Total tax provision	$ 6,819	$ 2,275	$ 2,911

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

	2005	2004 (restated)	2003 (restated)
Statutory rate	35%	35%	35%
Effect of losses and expenses not benefited	1	1	1
Rate differential on foreign earnings	55	12	(22)
Research and development benefit	(12)	8	(6)
State income taxes, net of federal benefit	(2)	(3)	3
Deferred tax on indefinite-lived assets	(24)	(21)	1
Change in valuation allowance	(108)	(48)	13
Effective tax rate	(55)%	(16)%	25%

(16) 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. Our allocation of certain expenditures benefiting multiple segments has been refined during 2005 and applied on a consistent basis for all period presented below. Included in the operating results of Corporate and Other are non-allocable corporate expenditures and expenses related to our research and development activities in the area of cardiology, the latter of which amounted to $16.8 million, $19.4 million and $12.8 million in 2005, 2004 and 2003, respectively. With respect to the cardiology expenditures in 2005, the amount included in Corporate and Other is net of $17.2 million of reimbursements received from ITI Scotland as part of the co-development arrangement that we entered into in February 2005. Total assets in the area of cardiology, which are included in Corporate and Other in the tables below, amounted to $41.2 million at December 31, 2005 and $8.6 million at December 31, 2004.

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 2005, 2004, and 2003 are as follows:

2005	Consumer Diagnostic Products	Vitamins and Nutritional Supplements	Professional Diagnostic Products	Corporate and Other	Total
			(in thousands)		
Net revenue to external customers	$ 166,928	$ 75,411	$ 179,511	$	$ 421,850
Operating income (loss)	$ 25,117	$ (7,010)	$ 2,179	$ (31,059)	$ (10,773)
Depreciation and amortization	$ 8,464	$ 3,460	$ 13,915	$ 1,917	$ 27,756
Restructuring charge	$ 4,797	$	$ 969	$	$ 5,766
Stock-based compensation	$	$	$	$ 169	$ 169
Assets	$ 253,063	$ 52,967	$ 434,796	$ 50,340	$ 791,166
Expenditures for property, plant and equipment	$ 8,020	$ 3,439	$ 6,578	$ 2,196	$ 20,233

2004	Consumer Diagnostic Products	Vitamins and Nutritional Supplements	Professional Diagnostic Products	Corporate and Other	Total
			(restated)		(restated)
			(in thousands)		
Net revenue to external customers	$ 164,211	$ 77,923	$ 131,857	$	$ 373,991
Operating income (loss)	$ 29,160	$ (1,003)	$ 5,840	$ (29,611)	$ 4,386
Depreciation and amortization	$ 9,642	$ 3,686	$ 9,430	$ 742	$ 23,500
Restructuring charge	$ 1,725	$	$	$	$ 1,725
Assets	$ 243,001	$ 48,072	$ 264,260	$ 12,936	$ 568,269
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)
			(in thousands)		
Net revenue to external customers	$ 134,877	$ 71,637	$ 88,644	$	$ 295,158
Operating income (loss)	$ 21,785	$ 3,556	$ 9,273	$ (19,780)	$ 14,834
Depreciation and amortization	$ 7,349	$ 3,632	$ 5,288	$ 166	$ 16,435
Stock-based compensation	$ 92	$	$ 12	$ 343	$ 447
Assets	$ 228,175	$ 52,973	$ 254,349	$ 5,032	$ 540,529
Expenditures for property, plant and equipment	$ 5,912	$ 1,496	$ 3,084	$ 643	$ 11,135

	2005	2004	2003
		(restated)	(restated)
		(in thousands)	
Revenue by Geographic Area:			
United States	$ 244,719	$ 222,640	$ 188,004
Europe	111,838	100,693	71,099
Other	65,293	50,658	36,055
	$ 421,850	$ 373,991	$ 295,158

	December 31,	
	2005	2004
	(in thousands)	
Long-lived Tangible Assets by Geographic Area:		
United States	$ 33,810	$ 29,946
United Kingdom	30,202	27,337
Ireland	1,114	5,897
Other	7,085	3,600
	$ 72,211	$ 66,780

(17) 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. IMI charged approximately $0.2 million during 2003 in transition service fees to IMT, which it believes to approximate arm's-length costs. These fees reduced our general and administrative expenses during 2003. The transition services provided by IMI and CDIL terminated in February 2003 and July 2002, respectively.

(18) 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, 2003	$ 7,538	$ 19,617	$ (19,663)	$ 7,492
Year ended December 31, 2004	$ 7,492	$ 27,908	$ (26,041)	$ 9,359
Year ended December 31, 2005	$ 9,359	$ 25,015	$ (24,626)	$ 9,748

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, 2003	$ 1,275	$ 1,810	$ (996)	$ 2,089
Year ended December 31, 2004	$ 2,089	$ 6,761	$ (4,724)	$ 4,126
Year ended December 31, 2005	$ 4,126	$ 10,057	$ (6,441)	$ 7,742

(19) Restructuring Activities

In connection with our acquisitions of the Unipath business, IMN, Ostex, Ischemia and BioStar, we recorded restructuring costs as part of the respective aggregate purchase prices in accordance with EITF No. 95-3 (Note 4). During 2004, we completed a plan of restructuring at our manufacturing operations at Unipath. During 2005, we completed a plan of restructuring at our operations at Ischemia and committed to a restructuring plan for BioStar, which is expected to be completed by the third quarter of fiscal year 2006. The following table sets forth the aggregate restructuring costs and balances recorded in connection with the restructuring activities of the acquired businesses, the 2004 restructuring activities at Unipath and the 2005 restructuring activities at Ischemia and BioStar:

	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, 2003	$ 2,272	$ 3,632	$ (2,081)	$ 129	$ 3,952
Year ended December 31, 2004	$ 3,952	$ 2,034	$ (3,467)	$ 107	$ 2,626
Year ended December 31, 2005	$ 2,626	$ 2,246	$ (1,858)	$ (147)	$ 2,867

(i) Represents foreign currency translation adjustment.

The following describes our restructuring plans for which we had remaining obligations as of December 31, 2005:

(a) Recent Restructuring Plans

On May 9, 2005, we committed to a plan to cease operations at our facility in Galway, Ireland. During 2005, we recorded a $5.1 million restructuring charge, of which $2.3 million related to severance, early retirement, outplacement services, $2.3 million related to impairment of fixed assets and inventory and $0.5 million related to facility closing costs relating primarily to this plan of termination.

The total restructuring charge for the year ended December 31, 2005 consisted of $4.1 million charged to cost of goods sold, $0.5 million charged to research and development, $0.3 million charged to general and administrative and $0.2 million charged to other expense. Of this total restructuring charge, $4.8 million and $0.3 million was included in our consumer diagnostic products and professional diagnostic products business segments, respectively. The total number of employees to be involuntarily terminated is 113, of which 98 were terminated during 2005 and the remaining 15 will be terminated during the first quarter of 2006. As of December 31, 2005, of the $2.3 million related to severance, early retirement and outplacement services, $0.6 million remained unpaid. Of the $0.5 million in facility closing cost, $0.4 million remained unpaid as of December 31, 2005. Including the charges recorded during the year, we expect the total restructuring charge primarily related to the closure of CDIL to be approximately $5.2 million, with additional charges relating principally to severance and facility closing costs of $0.1 million expected to be recorded in the first quarter of 2006 within the consumer diagnostic products segment. Upon liquidation of CDIL's remaining net assets, which is anticipated to occur during the first quarter of 2006, we expect to record a gain of approximately $3.6 million based on foreign currency exchange rates as of December 31, 2005 as the result of a reclassification of the cumulative translation adjustment to other income, net.

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, 2005. As of December 31, 2005, all restructuring costs have been paid.

(b) Restructuring Plans Related to Business Combinations

During the fourth quarter of 2005, we established a restructuring plan in connection with our acquisition of Biostar. We recorded a $0.5 million charge of which $0.4 million related to impairment of fixed assets and $0.1 million related to severance costs associated with a headcount reduction. The total number of employees to be involuntarily terminated is 12, of which none were terminated as of December 31, 2005. None of the costs recorded during 2005 were paid as of December 31, 2005. Although we believe our plan and estimated exit costs are reasonable, actual spending for exit activities may differ from current estimated exit costs, which might impact the final aggregate purchase price.

In connection with our acquisition of Ischemia in the first quarter of 2005, we established a restructuring plan whereby we have exited the current facilities of Ischemia in Denver, Colorado, and

combined its activities with our existing manufacturing and distribution facilities. Total severance costs associated with involuntarily terminated employees are estimated to be $1.6 million, of which $1.5 million has been paid as of December 31, 2005. We estimated costs to vacate the Ischemia facilities to be approximately $0.1 million, none of which has been paid as of December 31, 2005. We expect to pay the remaining costs during the first quarter of 2006. The total number of involuntarily terminated employees was 17, of which all were terminated as of December 31, 2005. Although we believe our plan and estimated exit costs are reasonable, actual spending for exit activities may differ from current estimated exit costs, which might impact the final aggregate purchase price.

As a result of the merger with Ostex (Note 4(c)), 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 was 38, of which all were terminated as of December 31, 2005. Total severance costs associated with employees to be terminated involuntarily was $1.6 million, of which substantially all has been paid as of December 31, 2005. Costs to vacate the Ostex facilities were $0.5 million, of which $0.1 million were paid as of December 31, 2005. Additionally, the remaining costs to exit operations, primarily facilities lease commitments, are $1.9 million, of which $1.6 million were paid as of December 31, 2005. Total unpaid exit costs amounted to $0.8 million as of December 31, 2005.

Immediately after the close of the acquisition, we reorganized the business operations of IMN to improve efficiencies and eliminate redundant activities on a company-wide basis. The restructuring affected all cost centers within the organization, but most significantly responsibilities at the sales and executive levels, as such activities were combined with 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, $0.1 million in restructuring costs remain unpaid as of December 31, 2005. 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, 2005, $1.3 million, adjusted for foreign exchange effect, in exit costs remained unpaid.

(20) 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, 2005. 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, 2005 and the balance sheets as of December 31, 2005 and 2004 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, 2005
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	$ 23,811	$ 235,141	$ 207,431	$ (59,926)	$ 406,457
License revenue		259	15,134		15,393
Net revenue	23,811	235,400	222,565	(59,926)	421,850
Cost of sales	24,846	187,744	116,847	(59,899)	269,538
Gross profit	(1,035)	47,656	105,718	(27)	152,312
Operating expenses:					
Research and development	374	6,796	23,822		30,992
Sales and marketing	2,849	35,761	33,493		72,103
General and administrative	12,410	16,927	30,484		59,821
Stock-based compensation	169				169
Total operating expenses	15,802	59,484	87,799		163,085
Operating (loss) income	(16,837)	(11,828)	17,919	(27)	(10,773)
Equity in earnings of subsidiaries, net of tax	13,537			(13,537)	
Interest expense, including amortization of discounts	(16,502)	(2,941)	(7,839)	5,487	(21,795)
Other income, net	1,461	6,762	17,442	(5,487)	20,178
(Loss) income before income taxes	(18,341)	(8,007)	27,522	(13,564)	(12,390)
Provision for income taxes	868	2,283	3,494	174	6,819
Net (loss) income	$ (19,209)	$ (10,290)	$ 24,028	$ (13,738)	$ (19,209)

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

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Net product sales	$ 20,842	$ 214,132	$ 180,685	$ (50,227)	$ 365,432
License revenue		114	8,445		8,559
Net revenue	20,842	214,246	189,130	(50,227)	373,991
Cost of sales	20,182	164,383	92,713	(50,291)	226,987
Gross profit	660	49,863	96,417	64	147,004
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)	6,682	10,107	64	4,386
Equity in earnings of subsidiaries, net of tax	7,394			(7,394)	
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	(15,548)	2,840	5,717	(7,330)	(14,321)
Provision (benefit) for income taxes	1,048	1,276	(458)	409	2,275
Net (loss) income	$ (16,596)	$ 1,564	$ 6,175	$ (7,739)	$ (16,596)

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	$ 165,832	$ 135,222	$ (38,341)	$ 285,430
License revenue		401	9,327		9,728
Net revenue	22,717	166,233	144,549	(38,341)	295,158
Cost of sales	19,964	120,631	64,220	(37,174)	167,641
Gross profit	2,753	45,602	80,329	(1,167)	127,517
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)	9,233	14,407	(1,167)	14,834
Equity in earnings of subsidiaries, net of tax	15,262			(15,262)	
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	9,151	5,989	12,853	(16,429)	11,564
Provision for income taxes	498	2,220	37	156	2,911
Net income	$ 8,653	$ 3,769	$ 12,816	$ (16,585)	$ 8,653

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING BALANCE SHEET
December 31, 2005
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
ASSETS					
Current Assets:					
Cash and cash equivalents	$ 1,196	$ 8,080	$ 24,994	$	$ 34,270
Accounts receivable, net of allowances	2,344	34,834	33,298		70,476
Inventories	7,518	42,794	26,997	(6,100)	71,209
Deferred tax assets			844		844
Prepaid expenses and other current assets	2,228	2,720	12,586		17,534
Intercompany receivables	38,919	34,346	19,974	(93,239)	
Total current assets	52,205	122,774	118,693	(99,339)	194,333
Property, plant and equipment, net	2,632	31,164	38,415		72,211
Goodwill	72,787	109,637	139,786		322,210
Other intangible assets with indefinite lives	8,700	12,420	42,622		63,742
Core technology and patents, net	28,269	5,556	30,225		64,050
Other intangible assets, net	20,321	18,429	21,739		60,489
Deferred financing costs, net, and other non-current assets	6,696	2,347	4,426		13,469
Deferred tax assets			662		662
Investment in subsidiaries	297,607	(1,162)		(296,445)	
Intercompany notes receivable	130,001	43,066		(173,067)	
Total assets	$ 619,218	$ 344,231	$ 396,568	$ (568,851)	$ 791,166
LIABILITIES AND STOCKHOLDERS' EQUITY					
Current liabilities:					
Current portion of long-term debt	$	$	$ 2,367	$	$ 2,367
Current portion of capital lease obligations		508	34		542
Accounts payable	1,549	25,438	15,168		42,155
Accrued expenses and other current liabilities	12,935	22,939	28,872		64,746
Intercompany payables	34,070	31,357	27,812	(93,239)	
Total current liabilities	48,554	80,242	74,253	(93,239)	109,810
Long-term liabilities:					
Long-term debt, net of current portion	169,456	60,000	29,161		258,617
Capital lease obligations, net of current portion		914	64		978
Deferred tax liabilities	3,900	5,964	8,889	128	18,881
Other long-term liabilities		278	5,294		5,572
Intercompany notes payable		42,331	130,736	(173,067)	
Total long-term liabilities	173,356	109,487	174,144	(172,939)	284,048
Stockholders' equity	397,308	154,502	148,171	(302,673)	397,308

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Total liabilities and stockholders' equity	$ 619,218	$ 344,231	$ 396,568	$ (568,851)	$ 791,166

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	41,152	19,815	(6,073)	61,234
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	93,025	78,675	(84,591)	151,757
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	261,274	(966)		(260,308)	
Intercompany notes receivable	114,439	15,089		(129,528)	
Total assets	$ 469,826	$ 284,242	$ 288,582	$ (474,381)	$ 568,269
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	21,654	22,180		56,242
Intercompany payables	13,640	15,964	48,914	(78,518)	
Total current liabilities	27,802	57,576	82,282	(78,518)	89,142
Long-term liabilities:					
Long-term debt, net of current portion.	169,256	20,000	12		189,268
Capital lease obligations, net of current portion		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
Stockholders' equity	271,416	148,198	118,137	(266,335)	271,416
Total liabilities and stockholders' equity	$ 469,826	$ 284,242	$ 288,582	$ (474,381)	$ 568,269

Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF CASH FLOWS
For the Year Ended December 31, 2005
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Operating Activities:					
Net (loss) income	$ (19,436)	$ (10,290)	$ 24,028	$ (13,511)	$ (19,209)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:					
Equity in earnings of subsidiaries, net of tax	(13,310)			13,310	
Interest expense related to amortization of non-cash original issue discount, non-cash beneficial conversion feature and deferred financing costs	1,181	665	499		2,345
Non-cash loss related to currency hedge agreement	217				217
Non-cash stock-based compensation expense	169				169
Non-cash value of settlement of litigation			(2,593)		(2,593)
Impairment of long-lived assets			1,740		1,740
(Gain) loss on sale of fixed assets		(13)	276		263
Depreciation and amortization	3,877	10,178	13,701		27,756
Deferred income taxes	665	2,231	2,899	174	5,969
Other non-cash items	141				141
Changes in assets and liabilities, net of acquisitions:					
Accounts receivable, net	316	12,039	(1,951)		10,404
Inventories	(1,558)	3,530	(6,046)	27	(4,047)
Prepaid expenses and other current assets	(950)	815	(7,463)		(7,598)
Intercompany payable (receivable)	3,390	(9,143)	5,055	698	
Accounts payable	(3,066)	4,914	4,353		6,201
Accrued expenses and other current liabilities	(915)	(2,092)	7,503		4,496
Other non-current liabilities		(3)	342		339
Net cash (used in) provided by operating activities	(29,279)	12,831	42,343	698	26,593

INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES
CONSOLIDATING STATEMENT OF CASH FLOWS (Continued)
For the Year Ended December 31, 2005
(in thousands)

	Issuer	Guarantor Subsidiaries	Non-Guarantor Subsidiaries	Eliminations	Consolidated
Cash Flows from Investing Activities:					
Purchases of property, plant and equipment	(613)	(6,851)	(12,769)		(20,233)
Proceeds from sale of property, plant and equipment		81	160		241
Cash paid to acquire Ostex, Inc, net of cash received		(141)			(141)
Cash paid to acquire IVC Industries, net of cash received	(63)				(63)
Cash paid to acquire ACS business			(4,971)		(4,971)
Cash paid to acquire Ischemia, net of cash received	(4,211)	115			(4,096)
Cash paid to acquire Binax, net of cash received	(9,528)	1,556			(7,972)
Cash paid to acquire the Determine business	(1,602)		(56,500)		(58,102)
Cash paid to acquire BioStar	(53,607)				(53,607)
Cash paid to acquire IDT Spain, net of cash received			(20,030)		(20,030)
(Increase) decrease in other assets	(128)	(282)	(1,377)		(1,787)
Net cash used in investing activities	(69,752)	(5,522)	(95,487)		(170,761)
Cash Flows from Financing Activities:					
Cash paid for financing costs	(148)	(1,388)	(1,337)		(2,873)
Proceeds from issuance of common stock, net of issuance costs	97,440				97,440
Net (repayments) proceeds under revolving line of credit	(77)	40,000	29,519		69,442
Proceeds from issuance of notes payable			269		269
Principal payments of capital lease obligations		(488)	(13)		(501)
Intercompany notes payable (receivable)	3,000	(41,000)	38,000		
Net cash provided by (used in) financing activities	100,215	(2,876)	66,438		163,777
Foreign exchange effect on cash and cash equivalents		96	(1,493)	(698)	(2,095)
Net increase in cash and cash equivalents	1,184	4,529	11,801		17,514
Cash and cash equivalents, beginning of year	12	3,551	13,193		16,756
Cash and cash equivalents, end of year	$ 1,196	$ 8,080	$ 24,994	$	$ 34,270

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	$ (16,596)	$ 1,564	$ 6,175	$ (7,739)	$ (16,596)
Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities:					
Equity in earnings of subsidiaries, net of tax	(7,394)			7,394	
Interest expense related to amortization of non-cash original issue discount, non-cash beneficial conversion feature and deferred financing costs	1,181	3,282	466		4,929
Non-cash gain related to interest rate swap agreement	(695)				(695)
Non-cash 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)	(7,686)	(1,826)	(64)	(11,073)
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	2,903	5,221		15,049
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
(restated)
(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 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 (repayments) proceeds under revolving 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	$ 8,653	$ 3,769	$ 12,816	$ (16,585)	$ 8,653
Adjustments to reconcile net income to net cash (used in) provided by operating activities:					
Equity in earnings of subsidiaries, net of tax	(15,262)			15,262	
Interest expense related to amortization of non-cash original issue discount, non cash beneficial conversion feature and deferred financing costs	454	587	524		1,565
Non-cash gain related to interest rate swap agreement	(528)				(528)
Non-cash 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	(2,174)	(1,871)	1,166	(2,584)
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	(5,439)	(6,466)		(8,020)
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 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

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