INVERNESS MEDICAL INNOVATIONS INC
Form 10-K
March 01, 2007

Table of Contents

**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)**

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

**For the fiscal year ended December 31, 2006**

**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 of 1933. Yes x No o

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

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 x 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 x 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 x

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, 2006 (the last business day of the registrant s most recently completed second fiscal quarter) was $690,432,458.

As of February 26, 2007, the registrant had 46,239,163 shares of common stock, par value $0.001 per share, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant s definitive Proxy Statement to be filed with the Securities and Exchange Commission on or prior to April 30, 2007 are incorporated by reference into Part III of this Form 10-K.

---

**TABLE OF CONTENTS**

PART I
ITEM 1. BUSINESS
GENERAL
RECENT DEVELOPMENTS
ITEM 1A. RISK FACTORS
ITEM 1B. UNRESOLVED STAFF COMMENTS
ITEM 2. PROPERTIES
ITEM 3. LEGAL PROCEEDINGS
ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.
PART II
ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES
ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA
ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS
ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK
ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA
ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE
ITEM 9A. CONTROLS AND PROCEDURES
REPORT OF THE INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
ITEM 9B. OTHER INFORMATION
PART III
ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE
ITEM 11. EXECUTIVE COMPENSATION
ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS
ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE
ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES
PART IV
ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES
SIGNATURES
INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES CONSOLIDATED FINANCIAL STATEMENTS
EX-2.10 ASSET PURCHASE AGREEMENT
EX-2.11 CONTRIBUTION AGREEMENT
EX-3.4 AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
EX-3.5 CERTIFICATE OF CORRECTION
EX-10.28 NINTH AMENDMENT AND CONSENT TO THIRD AMENDED AND RESTATED CREDIT AGREEMENT
EX-10.40 SUBUNDERLEASE, DATED 15 FEBRUARY 2007
EX-10.41 AMENDMENT NO. 4 TO 2001 STOCK OPTION AND INCENTIVE PLAN
EX-10.42 AMENDMENT NO. 5 TO 2001 STOCK OPTION AND INCENTIVE PLAN
EX-14.50 BUSINESS CONDUCT GUIDELINES
EX-21.1 LIST OF SUBSIDIARIES
EX-23.1 CONSENT OF BDO SEIDMAN, LLP
EX-31.1 CERTIFICATION OF CHIEF EXECUTIVE OFFICER
EX-31.2 CERTIFICATION OF CHIEF FINANCIAL OFFICER
EX-32.1 CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER

Table of Contents

## 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 markets. 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 proprietary lateral flow immunoassay technology and our strong intellectual property portfolio, and by making selected strategic acquisitions. We have an experienced research and development team and a continuing commitment to product development, and have a demonstrated capability for introducing new and innovative products through internal research and development efforts. We are presently exploring new opportunities in a variety of professional diagnostic and consumer-oriented applications, including immuno-diagnostics with a focus on cardiology, infectious disease and women s health.

Our objective is to be a leading provider of innovative rapid diagnostic products in cardiology to both consumer and professional diagnostic markets, while enhancing our current position as a leader in the professional rapid diagnostic test market though geographic and product line expansions and selective acquisitions. We plan to further expand our position in the consumer rapid diagnostic test product market, including the over-the-counter pregnancy and fertility/ovulation test market, through our pending joint venture with The Procter & Gamble Company, which is discussed further below.

Our principal executive offices are located at 51 Sawyer Road, Suite 200, Waltham, Massachusetts 02453 and our telephone number is (781) 647-3900. Our website 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, or the SEC. These reports may be accessed through our website s investor information page. We also make our code of ethics and certain other governance documents and policies available through this site.

Table of Contents

## RECENT DEVELOPMENTS

*Agreement with The Procter & Gamble Company to Form Consumer Diagnostics Joint Venture*

In December 2006, we signed a definitive agreement with The Procter & Gamble Company, or P&G, to form a 50/50 joint venture for the development, acquisition, manufacturing, marketing and sale of existing and to-be-developed consumer diagnostic products outside of the fields of cardiology and diabetes. In connection with this agreement, we will be contributing our related consumer diagnostic and monitoring assets, other than manufacturing and core intellectual property assets, to a new joint venture entity, and P&G will be acquiring its interest in the joint venture in consideration for a cash payment of $325.0 million to us. P&G will retain an option to require us to purchase its interest in the joint venture at fair market value during a 60-day period beginning on the fourth anniversary of the closing. Our primary role in the collaboration will be to develop and manufacture consumer diagnostic products, while P&G s primary role will be to market, sell and distribute existing and to-be-developed products. We will retain all rights with respect to the development and sale of cardiology diagnostic products and our professional point-of-care diagnostic businesses.

Following the completion of the transaction and the formation of the joint venture, we will cease to consolidate the operating results of our consumer diagnostics business, which represented $171.6 million of net product revenue in 2006 and instead will account for our 50% interest in the results of the joint venture under the equity method. In our capacity as the manufacturer of products for the joint venture, we will supply products to the joint venture and we will record revenue on those sales. No gain on the proceeds that we receive from P&G through the formation of the joint venture will be recognized in our financial statements until P&G s option to require us to purchase its interest in the joint venture at fair market value expires.

The transaction is expected to close in the first half of 2007, subject to the satisfaction of customary closing and other conditions.

*Sale of 6,900,000 Shares of Common Stock*

We recently raised net proceeds of approximately $261.3 million through an underwritten public offering of 6,900,000 shares of our common stock. In January 2007, we sold 6,000,000 shares to the public at $39.65 per share, and in February 2007, our underwriters exercised in full an option to purchase an additional 900,000 shares to cover over-allotments. Net proceeds include deductions for underwriting discounts and commissions and take into effect the reimbursement by the underwriters of a portion of our offering expenses. Of this amount, we used $44.9 million to repay principal outstanding and accrued interest on our term loan under our senior credit facility, with the remainder of the net proceeds retained for working capital and other general corporate purposes, including the financing of potential acquisitions or other investments.

*Acquisition of First Check*

In February 2007, we acquired substantially all of the assets of First Check Diagnostics LLC ( First Check ), a privately-held diagnostics company, for approximately $24.5 million in cash. In addition, we will pay an earn-out to First Check equal to the incremental revenue growth of the acquired products for 2007 and for the first nine months of 2008, as compared to the immediately preceding comparable periods.

First Check is the market leader in the rapidly-growing field of home testing for drugs of abuse, including marijuana, cocaine, methamphetamines and opiates. In addition, it offers tests, also sold through retail channels, for alcohol abuse, cholesterol monitoring and colon cancer screening.

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

Table of Contents

**Products**

*Consumer Diagnostic Products.* Our current consumer diagnostic products primarily 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 36 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. During 2006 we introduced, under the Clearblue Easy Digital brand, the first one piece digital pregnancy test, which contains both the absorbent wick and the digital read technology in a single disposable stick. 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 also sell Crystal Clear, the leading brand pregnancy test in Australia. We are also a major supplier of private label home pregnancy detection and fertility/ovulation prediction products and we currently supply Johnson & Johnson, who recently acquired the consumer healthcare business of 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.

In February 2007, we acquired First Check, the market leading brand of over-the-counter drugs of abuse tests for at-home testing for marijuana, cocaine, methamphetamines and opiates. We also acquired over-the-counter tests for alcohol abuse, cholesterol monitoring, and colon cancer screening which are also sold under the First Check brand.

*Vitamins and Nutritional Supplements.* We 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.

Table of Contents

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 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, RSV, Influenza A/B, strep throat, HIV, C.difficile, Lyme disease, chlamydia, H.pylori, fecal occult blood, D-dimer, mononucleosis and rubella. 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 brand names which include Acceava, BinaxNOW, BioStar OIA, Clearview, Determine, Signify, SureStep, Inverness Medical TestPack and Wampole.

*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.

Table of Contents

*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.

**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 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 radio, 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 parts of Western Europe using our own sales managers and a network of sales representatives. In other areas of the world, our consumer diagnostic products are sold though distribution contracts. Private label and contract manufacturing arrangements accounted for 34% of our consumer diagnostics business net product sales for 2006.

*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 2006, based on net product sales, together accounted for almost 63% of our net product sales for this segment. 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, Germany, Spain, Portugal, France and Israel, 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. We have also recently acquired distribution operations in Australia, Italy, Canada and Japan. 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, Spain, Portugal, France, Italy and Canada.

Under the terms of our acquisition of our Determine products from Abbott Laboratories in June 2005, Abbott distributes our Determine 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 Shanghai, China and Bedford, England. These facilities are ISO certified and registered with the United States Food and Drug Administration, or the FDA. 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 Johnson & Johnson. We purchase the electronic portion of our digital pregnancy and

Table of Contents

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 40% of the professional diagnostic products that we sell, based on net product sales for the fiscal year ended December 31, 2006 were manufactured by third parties. We manufacture the remainder, including substantially all of our BinaxNOW, BioStar OIA, Clearview, Signify, SureStep and Inverness Medical TestPack products, ourselves at our facilities in Hangzhou and Shanghai, China; Bedford, UK; Yavne, Israel; Scarborough, Maine and Louisville, Colorado. We also manufacture our Determine HIV products, acquired from Abbott Laboratories 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, or ITI, whereby ITI agreed to provide us with approximately £30.0 million over three years to partially fund research and development programs focused on identifying novel biomarkers and near-patient and home use tests for cardiovascular and other diseases. We agreed to invest £37.5 million in these programs over three years and we established a new research center in Stirling, Scotland where we conduct most of the funded research and development activities and where we will ultimately commercialize products arising from these efforts. ITI and Stirling will have exclusive rights to 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. Our other research and development activities are carried out in Bedford, England; Jena, Germany; Scarborough, Maine; and Yavne, Israel.

**Foreign Operations**

Our business relies heavily on our foreign operations. Five of our nine current manufacturing facilities are outside the United States, including our facility in Hangzhou, China, our primary consumer diagnostic products manufacturing facilities in Bedford, England and Shanghai, China, and our manufacturing operation in Matsudo, Japan. Since late 2005, we have also focused significant effort on expanding our worldwide distribution network supporting our professional diagnostics business by acquiring distribution operations in Spain, Australia, Germany, Japan, Italy and Canada. Approximately 41% of our net revenues were generated from outside of the United States during 2006. Our Clearblue products, pregnancy tests in particular, have historically been much stronger brands outside the United States, with 64% of our net product sales of Clearblue products coming from outside the United States during 2006. Our Inverness Medical TestPack and Determine 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

Table of Contents

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, Johnson & Johnson, Omega Pharma, Princeton BioMeditech, Arax and Rohto, among others, although we currently supply Johnson & Johnson and others with their pregnancy test products. Our competitors for the sale of fertility/ovulation prediction tests include Church & Dwight and Princeton BioMeditech, among others. For both pregnancy and fertility/ovulation tests worldwide, we also face growing competition from manufacturers located in Asia. 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. Our recently acquired First Check tests compete against over-the-counter diagnostic tests sold primarily by Phamatech, Inc., but also by other smaller competitors.

*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 U.S. Nutrition, Pharmavite and Leiner Health Products, also sell to private label customers and constitute our major competitors for private label business. In addition, there are several companies, such as Perrigo Company, 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 U.S. Nutrition, Wyeth, Pharmavite and GlaxoSmithKline.

*Professional Diagnostic Products.* In the rapid membrane market, our main competitors are Becton Dickinson, Quidel and Genzyme Diagnostics. 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 WHPM and Princeton BioMeditech. 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 with us 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.

Table of Contents

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. Through acquisitions 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 may 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 24 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

Table of Contents

products sold in the United States require FDA clearance to market under Section 510(k) 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.

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 January 31, 2007, we had approximately 2,561 employees, of which 1,056 employees are located in the United States. In addition, we utilize the services of temporary and contract employees, including approximately 1,000 contract employees leased from agencies in connection with our Chinese operations, as well as a number of consultants specializing in areas such as research and development, risk management, regulatory compliance, strategic planning and marketing.

Table of Contents

## ITEM 1A. RISK FACTORS

*The risks described below may materially impact your investment in our company or may in the future, and, in some cases already do, materially affect us and our business, financial condition and results of operations. You should carefully consider these factors with respect to 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, 2006, we had approximately $203.0 million in aggregate principal indebtedness outstanding, of which $53.0 million is secured indebtedness, and $110.0 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 8.75% senior subordinated notes, or the senior subordinated notes, we may incur additional indebtedness. During the fiscal years ended December 31, 2006 and 2005, we recorded $26.6 million and $21.8 million, respectively, of interest expense related to our indebtedness, which included $4.2 million and $2.3 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 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.

Table of Contents

**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 many of our acquisitions, including 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, or the 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; and the rapid diagnostics business that we acquired from ACON Laboratories, Inc., or the Innovacon business.

**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 these facilities and the limitation of our ability to borrow additional funds in the future.**

The agreements governing our senior credit 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, we may suffer a material adverse effect. 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.

Table of Contents

**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.**

Since commencing activities in November 2001, we have acquired and 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 Abbott rapid diagnostics business, Ischemia, Binax, the Determine business, BioStar, the Innovacon business and other smaller acquisitions. 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.

Table of Contents

**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.

**We may not complete our pending joint venture transaction with P&G.**

In December 2006, we announced that we had signed a definitive agreement with P&G to form a joint venture for the development, acquisition, manufacturing, marketing and sale of existing and to-be-developed consumer diagnostic products outside of the fields of cardiology and diabetes. The transaction is expected to close in the first half of 2007, subject to the satisfaction of customary closing and other conditions, such as that there be no material adverse change in our consumer diagnostics business, that the transaction be permitted under the indenture governing our senior subordinated notes or that we repay all of our outstanding senior subordinated notes and that we receive favorable tax

rulings from the Swiss tax authorities, the receipt of regulatory approvals, and obtaining certain third-party consents to the transaction. There can be no assurance that all of these conditions will be satisfied. If these conditions are not satisfied or waived, we may be unable to complete the joint venture. In addition, in connection with the regulatory approval process or the FTC s ongoing investigation relating to our acquisition of the Innovacon business, the terms of the joint venture may require modification, in which event we may not realize all of the benefits of the joint venture that we expect or the joint venture may not be completed at all.

**Even if we complete the P&G joint venture transaction, we may not realize all of its intended benefits.**

If we complete the P&G joint venture transaction, we may experience:

- difficulties in integrating the respective corporate cultures and business objectives of Inverness and P&G into the new joint venture;

Table of Contents

difficulties or delays in transitioning clinical studies;

diversion of our management s time and attention from other business concerns;

higher costs of integration at the joint venture than we anticipated;

difficulties in retaining key employees who are necessary to manage the joint venture; or

difficulties in working with an entity based in Switzerland and thus remote or inconvenient to our Waltham, Massachusetts headquarters.

For any of these reasons or as a result of other factors, we may not realize the anticipated benefits of the joint venture. P&G will retain an option to require us to purchase its interest in the joint venture at fair market value during the 60-day period beginning on the fourth anniversary of the closing.

Additionally, in connection with the completion of the joint venture, we will transfer or sell substantially all of the assets of our consumer diagnostics business, other than our manufacturing and core intellectual property assets, in exchange for $325.0 million in cash and a 50% interest in the joint venture. Our management will have broad discretion over the use and investment of this cash. Cash flow that we derive from the combination of any reinvestment of the $325.0 million we received in cash in connection with the transaction and our 50% interest in the joint venture may be less than the cash flow we derived from the disposed of assets.

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

**We 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, during 2006 we closed two manufacturing facilities and are shifting the production of products from these facilities to China. We have shifted the production of additional products to our manufacturing facilities in China. Moving the production of products is difficult and involves significant risk. Problems establishing relationships with local materials suppliers; acquiring or adapting the new facility and its equipment to the production of new products; hiring, training and retaining personnel and establishing and maintaining compliance with governmental regulations

and industry standards can cause delays and inefficiencies which could have a material negative impact on our financial performance. We also 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 by Abbott Laboratories, from whom we also receive support services related to this facility. Any event which negatively impacts our manufacturing facilities, our manufacturing systems or equipment, or our contract manufacturers or suppliers, including,

Table of Contents

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 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.

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.

Table of Contents

**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 2006, except in 2002 when they increased slightly as compared to 2001. We believe that these products have under-performed because they are, for the most part, aging brands with limited brand recognition that face increasing private label competition. The overall age of this product line means that we are subject to future distribution loss for under-performing brands, while our opportunities for new distribution on the existing product lines are limited. As a result, we do not expect significant sales growth of our existing brand name nutritional products and we may experience further declines in overall sales of our brand name nutritional products in the future.

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

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

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

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

Table of Contents

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, 2006 and 2005, approximately 46% and 58%, 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 63% of sales during 2006. 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 Johnson & Johnson, who recently acquired the consumer healthcare business of 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, with Johnson & Johnson, or JNJ, JNJ 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 JNJ 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 JNJ. As a result, if JNJ is unable to successfully market and sell its e.p.t pregnancy tests, or if other events adversely affect the volume of JNJ 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, 2006 and 2005, provided approximately 13% and 16%, 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 over the last several years and contributed to our losses in 2006.

Table of Contents

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

Approximately 41% and 42% of our net revenue was generated from outside the United States for the year ended December 31, 2006 and 2005, respectively. A significant number of our employees, including manufacturing, sales, support and research and development personnel, are located in foreign countries, including England, Scotland, Japan, China, 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. Five of our manufacturing operations are conducted outside the United States, in Bedford, England; Hangzhou and Shanghai, China; Matsudo, Japan and Yavne, Israel. We have consolidated much of our cardiovascular related research and development in Scotland and we intend to establish a significant manufacturing operation there. Approximately 41% and 42% of our net revenue was generated from outside the United States for the years ended December 31, 2006 and 2005, respectively. Our Clearblue pregnancy test product sales have historically been much stronger outside the United States, with 64% of net product sales of these products coming from outside the United States during the year ended December 31, 2006. In addition, the Abbott rapid diagnostics business 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 and our manufacturing facilities in China and Japan. 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.

Table of Contents

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

Table of Contents

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.

Table of Contents

**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 have continued 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.

**In March 2006, the Federal Trade Commission, or the FTC, opened a preliminary, non-public investigation into our acquisition of the Innovacon business to determine whether this acquisition may be anticompetitive. We cannot predict what the outcome of this investigation will be.**

In March, 2006, the FTC opened a preliminary, non-public investigation into our then pending acquisition of the Innovacon business we acquired from ACON Laboratories to determine whether this acquisition may be anticompetitive, and we subsequently received a Civil Investigative Demand and a subpoena requesting documents. We believe that we have fully responded to the Civil Investigative Demand and we are continuing to produce documents in connection with the subpoena and to otherwise cooperate with the FTC s investigation. We cannot predict whether the FTC will seek additional information or what the outcome of this investigation will be. The FTC generally has the power to commence administrative or federal court proceedings seeking injunctive relief or divestiture of assets. In the event that an order were to be issued requiring divestiture of significant assets or imposing other injunctive relief, our business, financial condition and results of operations could be materially adversely affected.

**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, 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.

Table of Contents

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 makes it difficult to analyze our results and to compare them from period to period, including our significant acquisitions of IVC Industries, Inc. in March 2002, Wampole in September 2002, Ostex in June 2003, ABI in August 2003, the Abbott rapid diagnostics product lines in September 2003, Binax and Ischemia in March 2005, the Determine business in June 2005, BioStar in September 2005, and the Innovacon business in March 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.

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

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

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

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

other developments affecting us or our competitors.

Table of Contents

**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. PROPERTIES

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 consumer and professional diagnostics operations are currently administered from a 150,000 square foot facility located in Bedford, England. We also manufacture products for these operations

Table of Contents

and conduct research and development activity at the Bedford facility. Our lease for this facility expires on September 27, 2021.

We also have manufacturing operations in Hangzhou and Shanghai, China; Scarborough, Maine; Louisville, Colorado; Yavne, Israel; Matsudo, Japan; Freehold and Irvington, New Jersey. We currently manufacture a portion of our professional diagnostic products, and some consumer diagnostic products, out of a newly constructed manufacturing facility of approximately 300,000 square feet in Hangzhou, China, which we own. We acquired this facility from ACON Laboratories, Inc. in May 2006. We currently manufacture a portion of our consumer diagnostic products out of approximately 25,000 square feet of space in Shanghai, China made available by our joint venture partner with the remainder manufactured at our Bedford, England facility. We manufacture certain of our professional diagnostic products out of a 64,000 square foot facility that we lease in Scarborough, Maine and out of a 75,000 square foot facility that we lease in Louisville, Colorado, portions of which we sublease to third parties. 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 are 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 manufacturing operations at our manufacturing facility in San Diego, California.

We also have leases or other arrangements for administrative or sales offices, lab space and warehouses in various locations worldwide.

## 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 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.

In March, 2006, the FTC opened a preliminary, non-public investigation into our then pending acquisition of the business we acquired from ACON Laboratories to determine whether this acquisition may be anticompetitive, and we subsequently received a Civil Investigative Demand and a subpoena requesting documents. We believe that we have fully responded to the Civil Investigative Demand and we are continuing to produce documents in connection with the subpoena and to otherwise cooperate with the FTC s investigation. We cannot predict whether the FTC will seek additional information or what the outcome of this investigation will be. The FTC generally has the power to commence administrative or federal court proceedings seeking injunctive relief or divestiture of assets. In the event that an order were to be issued requiring divestiture of significant assets or imposing other injunctive relief, our

business, financial condition and results of operations could be materially adversely affected.

Table of Contents

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

At a special meeting of stockholders held on December 15, 2006, the stockholders approved the matters set forth below. The stockholders approved and adopted (i) a proposal to increase the total number of shares of common stock that we are authorized to issue by 50,000,000 shares from 50,000,000 shares to 100,000,000 shares, and (ii) a proposal to increase the maximum number of shares of common stock available for issuance under the Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan from 6,074,081 to 8,074,081 shares.

The following table summarizes the votes for, against or withheld, with regard to each matter voted upon:

| Matter | For | Against | Withheld |
|---|---|---|---|
| Proposal to increase total number of authorized shares of common stock: | 23,091,744 | 1,196,816 | 45,066 |
| Proposal to increase maximum number of shares of common stock available for issuance under option plan: | 23,298,081 | 1,005,265 | 30,280 |

## PART II

## ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

### Market Information

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 2006 and 2005.

| | High | Low |
|---|---|---|
| **Fiscal 2006** | | |
| Fourth Quarter | $ 41.50 | $ 34.01 |
| Third Quarter | $ 36.02 | $ 25.99 |
| Second Quarter | $ 32.00 | $ 24.60 |
| First Quarter | $ 29.00 | $ 23.63 |
| **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 |

On February 26, 2007, there were 921 holders of record of our common stock.

### Dividend Policy

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.

Table of Contents

**Stock Performance Graph**

The following line graph compares the change in the cumulative total stockholder return on our common stock from December 31, 2001 through December 31, 2006. This graph assumes an investment of $100 on December 31, 2001 in our common stock, and compares its performance with the AMEX US Total Return Index and the AMEX Health Products & Services Total Return Index (the Current Indices ). We currently pay no dividends. The Current Indices reflect a cumulative total return based upon the reinvestment of dividends of the stocks included in those indices. Measurement points are December 31, 2001 and the last trading day of each subsequent fiscal quarter through December 31, 2006.

The comparisons shown in the graph below are based upon historical data. We caution that the stock price performance shown in the graph below is not necessarily indicative of, nor is it intended to forecast, the potential future performance of our common stock.

**Current Indices**

| Date | 12/31/01 | 12/31/02 | 12/31/03 | 12/31/04 | 12/30/05 | 12/29/06 |
|---|---|---|---|---|---|---|
| **IMA** | $ 100.00 | $ 72.85 | $ 120.66 | $ 139.06 | $ 131.36 | $ 214.40 |
| **AMEX US Total Return Index** | $ 100.00 | $ 81.74 | $ 110.63 | $ 127.83 | $ 138.33 | $ 160.48 |
| **AMEX Health Products & Services Total Return Index** | $ 100.00 | $ 69.12 | $ 121.08 | $ 124.55 | $ 107.72 | $ 138.96 |

The performance graph above shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (The Exchange Act ), or otherwise subject to the liability of that section. This graph will not be deemed incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Table of Contents

## ITEM 6. SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth selected consolidated financial data of our company as of and for each of the years in the five-year period ended December 31, 2006 and should be read in conjunction with Management s Discussion and Analysis of Financial Condition and Results of Operations and 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, 2006 and 2005 and for each of the three years in the period ended December 31, 2006 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, 2004, 2003 and 2002 have been derived from our consolidated financial statements not included herein, which were audited by BDO Seidman, LLP.

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.

| | For the Year Ended December 31, | | | | |
|---|---|---|---|---|---|
| | 2006 | 2005 | 2004 | 2003 | 2002(2) |
| | (in thousands, except per share data) | | | | |
| **Statement of Operations Data:** | | | | | |
| Net product sales | $ 552,130 | $ 406,457 | $ 365,432 | $ 285,430 | $ 200,399 |
| License and royalty revenue | 17,324 | 15,393 | 8,559 | 9,728 | 6,405 |
| Net revenue | 569,454 | 421,850 | 373,991 | 295,158 | 206,804 |
| Cost of sales | 340,231 | 269,538 | 226,987 | 167,641 | 114,653 |
| Gross profit | 229,223 | 152,312 | 147,004 | 127,517 | 92,151 |
| Operating expenses: | | | | | |
| Research and development | 53,666 | 30,992 | 31,954 | 24,367 | 14,508 |
| Sales and marketing | 94,445 | 72,103 | 57,957 | 52,504 | 39,570 |
| General and administrative | 71,243 | 59,990 | 52,707 | 35,812 | 38,628 |
| Loss on dispositions, net | 3,498 | | | | |
| Charge related to asset impairment | | | | | 12,682 |
| Operating income (loss) | 6,371 | (10,773) | 4,386 | 14,834 | (13,237) |
| Interest expense and other expenses, net | (17,486) | (1,617) | (18,707) | (3,270) | (5,955) |
| (Loss) income from continuing operations before provision for income taxes | (11,115) | (12,390) | (14,321) | 11,564 | (19,192) |
| Provision for income taxes | 5,727 | 6,819 | 2,275 | 2,911 | 3,443 |
| (Loss) income from continuing operations | $ (16,842) | $ (19,209) | $ (16,596) | $ 8,653 | $ (22,635) |

| | | | | | |
|---|---|---|---|---|---|
| (Loss) income from continuing operations available to common stockholders basic and diluted(1) | $ (16,842) | $ (19,209) | $ (17,345) | $ 7,695 | $ (34,583) |
| (Loss) income per common share(1): | | | | | |
| Basic(1) | $ (0.49) | $ (0.79) | $ (0.87) | $ 0.49 | $ (3.48) |
| Diluted(1) | $ (0.49) | $ (0.79) | $ (0.87) | $ 0.44 | $ (3.48) |

Table of Contents

| | 2006 | 2005 | December 31, 2004 | 2003 | 2002 |
|---|---|---|---|---|---|
| | | | (in thousands) | | |
| **Balance Sheet Data:** | | | | | |
| Cash and cash equivalents | $ 71,104 | $ 34,270 | $ 16,756 | $ 24,622 | $ 30,668 |
| Working capital | $ 133,313 | $ 84,523 | $ 62,615 | $ 44,693 | $ 27,685 |
| Total assets | $ 1,085,771 | $ 791,166 | $ 568,269 | $ 540,529 | $ 356,495 |
| Total debt | $ 202,976 | $ 262,504 | $ 191,224 | $ 176,181 | $ 104,613 |
| Redeemable convertible preferred stock | $ | $ | $ | $ 6,185 | $ 9,051 |
| Total stockholders equity | $ 714,138 | $ 397,308 | $ 271,416 | $ 265,173 | $ 161,849 |

(1) (Loss) income available to common stockholders and basic and diluted (loss) income per common share are computed as described in Notes 2(m) and 13 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

(2) Upon the adoption of Statement of Financial Accounting Standards, 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 before provision for income taxes 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.

Table of Contents

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

### Forward-Looking Statements

This Annual Report on Form 10-K, including this Item 7, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. 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 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 our pending joint venture with The Procter & Gamble Company, or P&G, the impact of our expanded distribution network, the impact of the consolidation of our manufacturing facilities on margins, the impact of improved margins on operating cash flow, new product introductions, research and development expenditures, 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.

### Overview

As a leading global manufacturer and supplier of rapid diagnostic products for consumer and professional markets, we are continually exploring new opportunities for our proprietary 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. As part of this strategy, we are focused on opportunities, including acquisitions and strategic partnerships, aimed at expanding both our product offerings and our distribution capability in the rapid diagnostic marketplace. Our 2006 acquisition of the assets of ACON Laboratories business of researching, developing, manufacturing, marketing and selling lateral flow immunoassay and directly-related products in the United States, Canada, Australia, Japan and most of western Europe, or the Innovacon business, not only expanded our product offerings but had an immediate positive impact on our operating results. We have also continued to expand the worldwide distribution network supporting our professional diagnostics segment which will ultimately enable us to get our future cardiology diagnostic products to the professional users critical to market acceptance. Since the beginning of the fourth quarter of 2005, we have acquired distributors in Spain, Australia, Canada, Germany, Italy and Japan.

We are also focused on improving our margins through consolidation of certain of our manufacturing operations at lower cost facilities. Our acquisition of the Innovacon business also represents a key component of this strategy. To date we have benefited from the higher margins that this business enjoys. These margins result from the lower costs associated with manufacturing at the new 300,000 square foot manufacturing facility located in Hangzhou, China, or the ABON facility, which we acquired in May 2006 as part of the transaction with ACON Laboratories. In 2007, we expect to begin to see improved margins on some of our existing products as we move production of certain products from higher costs facilities to the ABON facility.

Our agreement with P&G to form a 50/50 joint venture for the development, manufacturing, marketing and sale of existing and to-be-developed consumer diagnostic products outside of the fields of cardiology and diabetes presents us an exciting and unique opportunity. By leveraging P&G s marketing and distribution capabilities, we expect this partnership to simultaneously expand the reach of our over-the-counter diagnostic

Table of Contents

products, while enabling enhanced focus on our rapidly growing professional diagnostics segment and, in particular, on our cardiology development programs.

We also continue to emphasize new product development. This requires substantial investment and involves significant inherent risk. We intend to continue to devote substantial resources to research and development activities. We will also continue to aggressively defend our substantial intellectual property portfolio, which underlies our emphasis on new product development, against potential infringers.

**2006 Financial Highlights**

Net revenue in 2006 of $569.5 million increased by $147.6 million, or 35%, from $421.9 million in 2005 primarily as a result of our acquisition of the Innovacon business and businesses acquired during 2005, most notably Binax and the Determine business acquired from Abbott Laboratories, higher license and royalty revenue and, to a lesser extent, organic growth.

Gross profit increased by $76.9 million, or 50%, to $229.2 million in 2006 from $152.3 million in 2005 principally as a result of increased license and royalty revenue and from gross profit earned on incremental revenue from acquired businesses, primarily in our professional diagnostic business. Gross profit from our nutritional supplements business also increased in 2006, principally as a result of improved factory utilization as a result of increasing revenue and cost reduction initiatives in our private label manufacturing business. Offsetting these increases were a variety of charges totaling $9.8 million associated with the closures of our ABI operation in San Diego, California and our manufacturing facility in Galway, Ireland and non-cash stock-based compensation expense. Gross profit in 2005 was adversely impacted by $8.1 million associated with the closing of our Galway, Ireland manufacturing facility and with charges associated with excess inventories and a product recall.

We continue to invest aggressively in research and development of new products and technologies as evidenced by our increased research and development expense of $53.7 million in 2006 from $31.0 million in 2005. Expenditures in 2006 and 2005 are reported net of $16.6 million and $17.2 million, respectively, 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 $70.3 million in 2006 and $48.2 million in 2005, an increase of $22.1 million. The increase in spending resulted in part from expenditures of $8.9 million associated with our acquisitions of Clondiag and the Innovacon business, including a $5.0 million charge related to the write-off of in-process research and development projects that had not achieved technical feasibility as of the date of our acquisition of Clondiag. The remaining research and development spending primarily related to our continued significant investment in the development of products in the field of cardiology. Our co-development funding arrangement with ITI Scotland expires in March 2008 and we expect to receive approximately £10 million (or $19.6 million at December 31, 2006) of aggregate additional funding through the end of the arrangement.

**Results of Operations**

*Year Ended December 31, 2006 Compared to Year Ended December 31, 2005*

**Net Product Sales.** Net product sales increased by $145.7 million, or 36%, to $552.1 million in 2006 from $406.5 million in 2005. Excluding the unfavorable impact of currency translation, net product sales in 2006 grew by approximately $143.5 million, or 35%, over 2005. Of the currency adjusted increase, revenue increased as a result of our acquisitions of: (i) Binax in March 2005, which contributed revenue of $9.6 million, (ii) the Determine business in June 2005, which contributed revenue of $15.9 million, (iii) BioStar in September 2005, which contributed revenue of $21.0 million, (iv) IDT in September 2005, which contributed $10.4 million, (v) the Innovacon business in March 2006, which contributed $54.9 million, and (vi) various less significant acquisitions, which contributed an aggregate

of $1.9 million of such increase.

Table of Contents

**Net Product Sales by Business Segment.** Net product sales by business segment for 2006 and 2005 are as follows:

| | 2006 | 2005 | % Increase |
|---|---|---|---|
| | | (in thousands) | |
| Consumer diagnostic products | $ 171,607 | $ 161,695 | 6% |
| Vitamins and nutritional supplements | 82,051 | 75,411 | 9% |
| Professional diagnostic products | 298,472 | 169,351 | 76% |
| Net product sales | $ 552,130 | $ 406,457 | 36% |

*Consumer Diagnostic Products*

The currency adjusted increase in net product sales from our consumer diagnostic products was $8.3 million, or 5.1%, comparing 2006 to 2005. Of the currency adjusted increase, $7.4 million resulted from our acquisition of the Innovacon business in March 2006.

*Vitamins and Nutritional Supplements*

Our vitamins and nutritional supplements net product sales increased by $6.6 million, or 9%, comparing 2006 to 2005. The increase was driven primarily by our private label business.

*Professional Diagnostic Products*

The currency adjusted increase in net product sales from our professional diagnostic products was $128.6 million, or 75.9%, comparing 2006 to 2005. Of the currency adjusted increase, revenue increased as a result of our acquisitions of: (i) Binax in March 2005, which contributed revenue of $9.6 million, (ii) the Determine business in June 2005, which contributed revenue of $15.9 million, (iii) BioStar in September 2005, which contributed revenue of $21.0 million, (iv) IDT in September 2005, which contributed revenue of $10.4 million, (v) the Innovacon business in March 2006, which contributed $47.5 million and (vi) various less significant acquisitions, which contributed an aggregate of $1.9 million of such increase. Organic growth, particularly from our highly differentiated respiratory products, also contributed to the growth.

**Net Product Sales by Geographic Location.** Net product sales by geographic location for 2006 and 2005 are as follows:

| | 2006 | 2005 | % Increase |
|---|---|---|---|
| | | (in thousands) | |
| United States | $ 323,046 | $ 234,229 | 38% |
| Europe | 134,528 | 108,981 | 23% |
| Other | 94,556 | 63,247 | 50% |
| Net product sales | $ 552,130 | $ 406,457 | 36% |

Net product sales of $323.0 million and $234.2 million generated in the United States were approximately 59% and 58% of total net product sales for the year ended December 31, 2006 and 2005, respectively. The growth in net product sales in all geographic regions resulted from the various acquisitions discussed above, and organic growth.

**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 $1.9 million, or 13%, to $17.3 million in 2006 from $15.4 million in 2005. The increase primarily relates to royalty revenue received as a result of the settlement and licensing arrangements that we entered into with Quidel Corporation in April 2005 and Vedalab in November 2006.

**Gross Profit and Margin.** Gross profit increased by $76.9 million, or 50%, to $229.2 million in 2006 from $152.3 million in 2005. Gross profit during 2006 benefited from higher than average margins earned on

Table of Contents

revenue from our recently acquired businesses and from favorable product mix. Included in cost of sales during 2006 was a restructuring charge of $9.5 million related to the closure of our ABI operation in San Diego, California, along with the write-off of fixed assets at other facilities impacted by our 2006 restructuring plans and the closure of CDIL, our manufacturing facility in Galway, Ireland. Cost of sales during 2006 also included a $0.4 million charge for stock-based compensation related to our January 1, 2006 adoption of SFAS No. 123-R, *Share-Based Payment*. Cost of sales during 2005 included: (i) the inclusion in cost of sales of a $4.1 million charge principally associated with our decision to close our Galway, Ireland 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.

Cost of sales included amortization expense of $11.2 million and $7.2 million in 2006 and 2005, respectively.

Overall gross margin was 40% in 2006 compared to 36% in 2005. Overall gross margin in 2006 was adversely affected by the $9.5 million restructuring charge and $0.4 million stock-based compensation charge discussed above. 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.

**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 and royalty revenue. Gross profit from net product sales increased by $75.8 million to $217.3 million in 2006 from $141.5 million in 2005. Gross profit from net product sales by business segment for 2006 and 2005 is as follows:

| | 2006 | 2005 | % Increase |
|---|---|---|---|
| | | (in thousands) | |
| Consumer diagnostic products | $ 82,658 | $ 76,515 | 8% |
| Vitamins and nutritional supplements | 5,037 | 2,738 | 84% |
| Professional diagnostic products | 129,636 | 62,252 | 108% |
| Gross profit from net product sales | $ 217,331 | $ 141,505 | 54% |

*Consumer Diagnostic Products*

Gross profit from our consumer diagnostic product sales increased $6.1 million, or 8%, comparing 2006 to 2005. Cost of sales for 2006 included restructuring charges totaling $2.2 million related to the closure of our CDIL manufacturing facility and a $0.4 million charge for stock-based compensation. Included in cost of sales for 2005, and adversely effecting gross profit, was a $4.1 million charge principally associated with our decision to close our CDIL manufacturing facility.

As a percentage of our consumer diagnostic net product sales, gross profit was 48% for 2006 compared to 47% in 2005. The increase in gross profit from our consumer diagnostic product sales resulted from a change in product mix.

*Vitamins and Nutritional Supplements*

Gross profit in our vitamins and nutritional supplements business increased $2.3 million, or 84%, comparing 2006 to 2005. The increase is primarily the result of improved factory utilization and our cost reduction initiatives in our private label manufacturing business.

As a percentage of vitamin and nutritional supplements net product sales, gross profit for our vitamins and nutritional supplements business was 6% in 2006 compared to 4% in 2005.

Table of Contents

*Professional Diagnostic Products*

Gross profit from our professional diagnostic products increased by $67.4 million, or 108%, comparing 2006 to 2005, principally as a result of gross profit earned on revenue from acquired businesses, as discussed above, offset by a $7.2 million restructuring charge to cost of sales associated with management s decision to close our ABI operations in San Diego, California. Reducing gross profit 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.

As a percentage of our professional diagnostic net product sales, gross profit from our professional diagnostic product sales was 43% in 2006, compared to 37% in 2005.

**Research and Development Expense.** Research and development expense increased by $22.7 million, or 73%, to $53.7 million in 2006 from $31.0 million in 2005. Research and development expense in 2006 and 2005 is reported net of co-development funding of $16.6 million and $17.2 million, respectively, arising from the co-development funding arrangement that we entered into with ITI in February 2005. The year over year increase in research and development expense is primarily the result of increased spending related to our cardiology research programs, $8.9 million of spending related to our 2006 acquisitions, a $2.9 million charge related to the write-off of fixed assets impacted by our restructuring plans and a $1.4 million charge for stock-based compensation related to our January 1, 2006 adoption of SFAS No. 123-R. Included in the $8.9 million of additional spending related to recent acquisitions is a $5.0 million charge related to the write-off of in-process research and development projects that had not achieved technical feasibility as of the date of our acquisition of Clondiag.

Amortization expense of $3.3 million and $2.3 million was included in research and development expense for 2006 and 2005, respectively.

Research and development expense as a percentage of net product sales increased to 10% for 2006, from 8% for 2005.

**Sales and Marketing Expense.** Sales and marketing expense increased by $22.3 million, or 31%, to $94.4 million in 2006, from $72.1 million in 2005. The increase in sales and marketing expense is primarily attributed to our expanded sales and marketing infrastructure to support the growth in our professional diagnostics business, with additional expense of approximately $16.0 million related to our acquisitions of Binax, the Determine business, BioStar and IDT during 2005 and our acquisitions of Clondiag and the Innovacon business during 2006. Approximately $1.3 million of the increase in sales and marketing expense resulted from our increased advertising efforts to promote our premium consumer diagnostic products in 2006. Sales and marketing for 2006 also included a charge of $0.7 million for stock-based compensation related to our January 1, 2006 adoption of SFAS No. 123-R.

Amortization expense of $6.8 million and $2.9 million was included in sales and marketing expense for 2006 and 2005, respectively.

Sales and marketing expense as a percentage of net product sales decreased to 17% for 2006, from 18% for 2005.

**General and Administrative Expense.** General and administrative expense increased by $11.3 million, or 19%, to $71.2 million in 2006, from $60.0 million in 2005. Of the increase in general and administrative expense, approximately $12.2 million resulted from additional spending related to our acquisitions of Binax, the Determine business, BioStar and IDT which were completed during 2005 and to our 2006 acquisitions of Clondiag and the

Innovacon business. The increase in general and administrative expense during 2006 was partially offset by a decrease in legal expenses of $4.7 million. Also included in general and administrative expense is a $3.0 million charge for stock-based compensation related to our January 1, 2006 adoption of SFAS No. 123-R.

Table of Contents

Amortization expense included in general and administrative expense was $0.4 million for both 2006 and 2005.

General and administrative expense as a percentage of net revenue decreased to 13% for 2006, from 14% for 2005.

**Loss on Dispositions, Net.** During 2006, we recorded a net loss on dispositions of $3.5 million. Included in this charge is a loss of $4.9 million associated with management s decision to dispose of our Scandinavian Micro Biodevices ApS, or SMB, research operation. The $4.9 million charge includes a loss of $2.0 million on impaired assets, most of which represents goodwill associated with SMB, and a $2.9 million loss on the sale of SMB, which was finalized during the fourth quarter of 2006. The $4.9 million loss is offset by a $1.4 million gain on the sale of an idle manufacturing facility in Galway, Ireland, as a result of our 2005 restructuring plan.

**Interest Expense.** Interest expense for 2006 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. Interest expense for 2005 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 increased by $4.8 million, or 22%, to $26.6 million in 2006, from $21.8 million in 2005. In 2006, we recorded a charge of $1.3 million related to prepayment penalties and the write-off of debt origination costs resulting from the early repayment of our $20.0 million, 10% subordinated promissory notes on September 8, 2006. In addition to the $1.3 million charge, higher applicable interest rates on the senior credit facility during 2006, compared to 2005, and an increase in the amortization of deferred financing costs related to the debt refinancings that occurred later in 2005 and during the first quarter of 2006, also contributed to the increase in interest expense for 2006.

**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:

| | 2006 | 2005 |
|---|---|---|
| | (in thousands) | |
| Interest income | $ 1,693 | $ 1,035 |
| Foreign exchange gains (losses), net | 2,643 | (340) |
| Other | 4,748 | 19,483 |
| Other income (expense), net | $ 9,084 | $ 20,178 |

Other income (expense), net for 2006 includes a foreign exchange gain of $4.3 million associated with the closure of our Galway, Ireland manufacturing operation and $4.7 million in other income, related to the portion of our settlement with Vedalab relating to periods prior to 2006.

Other income (expense), net for 2005 includes the following items: (i) $15.0 million in other 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 Princeton BioMeditech Corporation, or PBM.

**Provision for Income Taxes.** Provision for income taxes decreased by $1.1 million, or 16%, to $5.7 million in 2006, from $6.8 million in 2005. The effective tax rate in 2006 was (52)%, compared to (55)% in 2005. The decrease in the provision for income taxes from 2005 to 2006 is primarily related to taxes on foreign income. The primary components of the 2006 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

Table of Contents

tax liabilities is approximately $3.4 million. 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.

**Net (Loss) Income.** We incurred a net loss of $16.8 million in 2006, while we incurred a net loss of $19.2 million in 2005. Net loss per common share available to common stockholders was $0.49 per basic and diluted common share in 2006, as compared to net loss of $0.79 per basic and diluted common share in 2005. The net loss in 2006 and 2005 resulted from the various factors as discussed above. See Note 13 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, 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 in March 2005, contributed $18.4 million of such increase, (ii) the Determine rapid diagnostics business, acquired in June 2005, contributed revenues of $17.2 million, (iii) BioStar, acquired in September 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:

| | 2005 | 2004 | % Increase (Decrease) |
|---|---|---|---|
| | | (in thousands) | |
| 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% |
| Net product sales | $ 406,457 | $ 365,432 | 11% |

*Consumer Diagnostic Products*

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.

*Vitamins and Nutritional Supplements*

Net product sales of our vitamins and nutritional supplements decreased by $2.5 million, or 3%, comparing 2005 to 2004. The decrease was primarily due to 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.

*Professional Diagnostic Products*

The currency adjusted increase in net product sales from our professional diagnostic products was $40.8 million, or 31%, 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.

Table of Contents

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

| | 2005 | 2004 | % Increase |
|---|---|---|---|
| | | (in thousands) | |
| United States | $ 234,229 | $ 218,251 | 7% |
| Europe | 108,981 | 98,136 | 11% |
| Other | 63,247 | 49,045 | 29% |
| 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 related 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 and royalty 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 suffered from excess capacity in the industry and increasing price competition.

Cost of sales included amortization expense of $7.2 million and $5.5 million in 2005 and 2004, respectively.

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 and royalty 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:

| | 2005 | 2004 | % Increase (Decrease) |
|---|---|---|---|

| | | | |
|---|---|---|---|
| | | **(in thousands)** | |
| 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% |
| 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.

Table of Contents

*Consumer Diagnostic Products*

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 a change in product mix.

*Vitamins and Nutritional Supplements*

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 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.

*Professional Diagnostic Products*

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.

Amortization expense of $2.3 million and $0.8 million was included in research and development expense for 2005 and 2004, respectively.

Research and development expense as a percentage of net product sales is 8% and 9% for 2005 and 2004, respectively.

**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.

Amortization expense of $2.9 million and $3.9 million was included in sales and marketing expense for 2005 and 2004, respectively.

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

Table of Contents

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 PBM.

Amortization expense of $0.4 million and $0.2 million was included in general and administrative expense for 2005 and 2004, respectively.

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:

| | 2005 | 2004 |
|---|---|---|
| | (in thousands) | |
| Interest income | $ 1,035 | $ 1,050 |
| Foreign exchange (losses) gains, net | (340) | (720) |
| Other | 19,483 | 3,077 |
| 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 in income, 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.

Table of Contents

**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 13 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 and expected funding resulting from our co-development funding agreement with ITI 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 our operating cash flow, which we expect to improve as we improve our operating margins and 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. If we raise additional funds by issuing equity or convertible securities, dilution to then existing stockholders may result.

*Summary of Changes in Cash Position*

As of December 31, 2006, we had cash and cash equivalents of $71.1 million, a $36.8 million increase from December 31, 2005. Our primary sources of cash during 2006, included $235.0 million in proceeds from the issuance of our common stock, including common stock issues under employee stock option and stock purchase plans, $14.7 million in proceeds from the repayment of notes receivable and $34.3 million from operating activities during 2006. Our investing activities during 2006 used $178.8 million of cash and consisted primarily of $131.5 million of cash used for acquisitions, $12.6 million used for the purchase of available-for-sale securities, $13.2 million used for minority interest and other investments, $19.7 million used for capital equipment purchases, offset by $2.2 million of net proceeds from the sale of our Galway, Ireland facility and sales of capital equipment, and a $4.1 million decrease in other assets. Our non-equity financing activities, primarily related to our senior credit facility and the 10% subordinated promissory notes, used cash of $70.6 million during 2006. Fluctuations in foreign currencies favorably impacted our cash balance by $2.4 million during 2006.

*Cash Flows from Operating Activities*

Net cash provided by operating activities during 2006 was $34.3 million, an increase of $7.7 million over the prior year. Our net loss during 2006 of $16.8 million was funded by our net cash from operating activities, along with a

$10.3 million increase in working capital as offset by $39.4 million of depreciation and amortization and $22.0 million of other non-cash items. The $10.3 million increase in working capital was primarily driven by an increase in our accounts receivable over prior year.

Table of Contents

*Cash Flows from Investing Activities*

During 2006, we paid $131.5 million in cash for acquisitions and transaction-related costs, net of cash acquired, primarily with respect to our acquisitions of Clondiag and the Innovacon business.

On February 28, 2006, we acquired 67.45% ownership of Clondiag, a privately-held company located in Jena in Germany which has developed a multiplexing technology for nucleic acid and immunoassay-based diagnostics and, on August 31, 2006, we acquired the remaining 32.55%. The aggregate purchase price for Clondiag was $24.4 million, consisting of $17.7 million in cash, 243,398 shares of our common stock valued at $6.5 million, $0.1 million direct acquisition costs and a $0.1 million remaining obligation. The terms of the Clondiag acquisition also provide for $8.9 million of contingent consideration, 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 acquisition date.

On March 31, 2006, we acquired the Innovacon business, although this acquisition involved several stages and payments during 2006. The aggregate purchase price for the acquisition of the Innovacon business, including the acquisition of the ABON facility in May 2006, was $184.1 million, consisting of cash payments totaling $112.0 million, 1,871,250 shares of our common stock valued at $53.0 million, $9.1 million in estimated direct acquisition costs and an additional liability of $10.0 million payable to the sellers on a deferred payment date. In connection with this acquisition, we also entered into an agreement for the purchase of ACON Laboratories lateral flow immunoassay sales and distribution business in all territories not included as part of the Innovacon business acquired during 2006. Under the terms of this agreement, in the event that this business achieves a specified level of profitability, we will acquire this business in 2009 for a formulaic price based on the revenues and earnings of the business. Alternatively, we may elect not to complete the acquisition of the business in exchange for a payment equal to 15% of the purchase price that would have been due had we elected to complete the acquisition.

In addition, on February 5, 2007, we acquired substantially all of the assets of First Check Diagnostics LLC, or First Check, a privately-held diagnostics company, for approximately $24.5 million in cash. In addition, we are obligated to pay an earn-out to First Check equal to the incremental revenue growth of the acquired products for 2007 and for the first nine months of 2008, as compared to the immediately preceding comparable periods.

During 2006, we purchased $12.6 million worth of marketable equity securities which we intend to hold indefinitely and therefore carry on our consolidated balance sheet as available-for-sale securities. These securities were recorded at their fair market value as of December 31, 2006.

Other cash investments made during 2006 include a 40% investment in Vedalab, a French manufacturer and supplier of rapid diagnostic tests in the professional markets. The aggregate purchase price was $9.7 million which consisted of $7.6 million in cash, 49,787 shares of our common stock with an aggregate fair value of $2.0 million and $0.1 million in estimated direct acquisition costs. Under the terms of the agreement, we also settled an on-going patent infringement claim with Vedalab, resulting in a settlement payment to us of $5.1 million.

*Cash Flows from Financing Activities*

On February 8 and 9, 2006, we sold an aggregate 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 August 23, 2006, we sold an aggregate 5,000,000 shares of our common stock at $30.25 per share to funds affiliated with 17 accredited institutional investors in a private placement. Proceeds from the private placement were approximately $145.5 million, net of issuance costs of $5.7 million. Of this amount, we used $41.3 million for payments related to our ABON acquisition, $5.3 million to purchase the remaining 32.55% of Clondiag, repaid principal outstanding under our senior credit facility of $54.0 million and repaid principal

Table of Contents

and interest outstanding, along with a prepayment penalty, under our 10% subordinated promissory notes of $20.8 million, with the remainder of the net proceeds retained for general corporate purposes.

On January 31, 2007, we sold an aggregate 6,000,000 shares of our common stock at $39.65 per share through an underwritten public offering, and on February 5, 2007, our underwriters exercised in full an option to purchase an additional 900,000 shares to cover over-allotments. Proceeds from the offering were approximately $261.3 million, net of issuance costs of $12.3 million, which include deductions for underwriting discounts and commissions and take into effect the reimbursement by the underwriters of a portion of our offering expenses. Of this amount, we used $44.9 million to repay all principal and accrued interest owing on the term loan under our senior credit facility, with the remainder of the net proceeds retained for working capital and other general corporate purposes.

In December 2006, we signed a definitive agreement with P&G to form a 50/50 joint venture for the development, manufacturing, marketing and sale of existing and to-be-developed consumer diagnostic products outside of the fields of cardiology and diabetes. In connection with this agreement, we will contribute our related consumer diagnostic and monitoring assets, other than manufacturing and core intellectual property assets, to a new joint venture entity, and P&G will acquire its interest in the joint venture in consideration for a cash payment of $325.0 million. Our primary role in the collaboration will be to develop and manufacture consumer diagnostic products, while P&G s primary role will be to market, sell, and distribute existing and to-be-developed products. We will retain all rights with respect to the development and sale of cardiology diagnostic products and our professional point of care diagnostic businesses. Following the completion of the transaction and the formation of the joint venture, we will cease to consolidate the operating results of our formerly wholly-owned consumer diagnostics business and instead will account for our 50% interest in the results of the joint venture under the equity method. In addition, because we will share control of the joint venture with P&G we may not have access to cash generated through the operations of the joint venture and, in certain circumstances, we could be required to provide working capital to the joint venture. Under the terms of our agreement with P&G, P&G can require us to repurchase its interest in the joint venture at market value after the fourth anniversary of the closing.

Our primary senior credit facility with a group of banks, as amended, consists of a $45.0 million U.S. term loan and revolving lines of credit in the aggregate amount of up to $110.0 million, subject to continuing covenant compliance. Our aggregate indebtedness under the senior credit facility was $44.8 million as of December 31, 2006, outstanding under the U.S. term loan. On February 1, 2007, we paid all remaining principal and accrued interest owing under our senior credit facility.

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, 2006, the applicable interest rate under the revolving lines of credit, including the applicable margin, ranged from 6.85% to 9.35%.

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 our subsidiaries in Israel, China, Japan, Australia and Sweden, 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

Table of Contents

agreement currently prohibits us from paying dividends. We are currently in compliance with the covenants, as amended.

In February 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. 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. As of December 31, 2006, accrued interest related to the bonds amounted to $4.9 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.

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.

As of December 31, 2006, we had an aggregate of $1.0 million in outstanding capital lease obligations which are payable through 2009.

*Income Taxes*

As of December 31, 2006, we had approximately $188.2 million of domestic net operating loss carryforwards and $45.9 million of foreign net operating loss, or NOL, carryforwards, respectively, which either expire on various dates through 2026 or can be carried forward indefinitely. These losses are available to reduce federal and foreign taxable income, if any, in future years. These losses are also subject to review and possible adjustments by the applicable taxing authorities. In addition, the domestic operating loss carryforward amount at December 31, 2006 included approximately $70.5 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, 2006 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, 2006.

Table of Contents

**Contractual Obligations**

The following table summarizes our principal contractual obligations as of December 31, 2006 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** | **2007** | **2008-2009** | **2010-2011** | **Thereafter** |
| | | | (in thousands) | | |
| Long-term debt obligations(1) | $ 201,977 | $ 51,830 | $ 147 | $ | $ 150,000 |
| Capital lease obligations(2) | 1,066 | 643 | 415 | 8 | |
| Operating lease obligations(3) | 67,803 | 10,454 | 16,146 | 10,441 | 30,762 |
| Long-term and other liabilities(4) | 6,442 | 3,103 | 1,992 | 1,347 | |
| Minimum royalty obligations | 260 | 220 | 40 | | |
| Purchase obligations capital expenditure | 8,813 | 8,813 | | | |
| Purchase obligations other(5) | 48,044 | 47,566 | 478 | | |
| Remaining obligations Innovacon business(6) | 17,158 | 17,158 | | | |
| Interest on debt(7) | 67,828 | 13,128 | 26,256 | 26,256 | 2,188 |
| Total | $ 419,391 | $ 152,915 | $ 45,474 | $ 38,052 | $ 182,950 |

(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 $1.0 million in technology license payment obligations and $5.4 million in pension obligations.

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

(6) In connection with our acquisition of the Innovacon business, we are obligated to make a $6.0 million payment for the remaining first territory business and a $1.1 million payment related to one European customer that has continued to take supply from the seller. Additionally, we are required to make a $10.0 million payment payable to the sellers on the deferred payment date.

(7) Amounts are based on $150.0 million senior subordinated notes. Amounts exclude interest on all other debt due to variable interest rates. See Note 6 of our consolidated financial statements included elsewhere in this Annual Report on Form 10-K.

As of December 31, 2006, we had outstanding material contingent contractual obligations related to our acquisitions of Binax and Clondiag. With respect to Binax, the terms of the acquisition agreement 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. With respect to the acquisition of Clondiag, the terms of the acquisition agreement provide for $8.9 million of contingent consideration, 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 acquisition date. The contingent considerations will be accounted for as increases in the aggregate purchase prices if and when the contingencies occur.

**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

Table of Contents

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, 2006 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 revenue is derived from product sales. We recognize revenue upon title transfer of the products to third-party customers, less a reserve for estimated product returns and allowances. Determination of the reserve for estimated product returns and allowances is based on our management s analyses and judgments regarding certain conditions, as discussed below in the critical accounting policy Use of Estimates for Sales Returns and Other Allowances and Allowance for Doubtful Accounts. Should future changes in conditions prove management s conclusions and judgments on previous analyses to be incorrect, revenue recognized for any reporting period could be adversely affected.

In connection with the acquisition of the Abbott rapid diagnostics business in September 2003 and the Determine business in June 2005 from Abbott Laboratories, 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, subject to certain extensions. 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 the Company records 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 $52.8 million, $51.2 million and $55.2 million, or 10%, 13% and 15%, respectively, of net product sales in 2006, 2005 and 2004, 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

Table of Contents

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 $100.4 million and $70.5 million, net of allowances for doubtful accounts of $8.4 million and $9.7 million, as of December 31, 2006 and December 31, 2005, 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 $78.3 million and $71.2 million, net of a provision for excess and obsolete inventory of $8.2 million and $7.7 million, as of December 31, 2006 and 2005, 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, 2006, the balances of property, plant and equipment, goodwill and other intangible assets, net of accumulated depreciation and amortization, were $82.3 million, $439.4 million and $239.6 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

Table of Contents

determine that shorter estimated useful lives are more appropriate. In that event, we will be required to record additional depreciation and amortization in future periods, which will reduce our earnings.

*Valuation of Goodwill*

We have goodwill balances related to our consumer diagnostics and professional diagnostics reporting units, which amounted to $86.0 million and $353.4 million, respectively, as of December 31, 2006. As of September 30, 2006, 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, 2006, 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, 2006, 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, 2006, future events could cause us to conclude otherwise.

*Stock-Based Compensation*

As of January 1, 2006, we account for stock-based compensation in accordance with SFAS No. 123-R, *Share-Based Payment*. Under the fair value recognition provisions of this statement, share-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the vesting period. Determining the fair value of share-based awards at the grant date requires judgment, including estimating our stock price volatility and employee stock option exercise behavior. If actual results differ significantly from these estimates, stock-based compensation expense and our results of operations could be materially impacted.

Our expected volatility is based upon the historical volatility of our stock. We have chosen to utilize the simplified method to calculate the expected life of options which averages an award s weighted average vesting period and its contractual term. As stock-based compensation expense is recognized in our consolidated statement of operations is based on awards ultimately expected to vest, the amount of expense has been reduced for estimated forfeitures. SFAS No. 123-R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. Forfeitures were estimated based on historical experience. If factors change and we employ different assumptions in the application of SFAS No. 123-R, the compensation expense that we record in future periods may differ significantly from what we have recorded in the current period.

*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

Table of Contents

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 $107.6 million as of December 31, 2006 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.

*Loss 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.

**Recent Accounting Pronouncements**

*Recently Issued Standards*

In February 2006, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 155, *Accounting for Certain Hybrid Financial Instruments*, which amends SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* and SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities.* SFAS No. 155 simplifies the accounting for certain derivatives embedded in other financial instruments by allowing them to be accounted for as a whole if the holder elects to account for the whole instrument on a fair value basis. SFAS No. 155 also clarifies and amends certain other provisions of SFAS No. 133 and SFAS No. 140. SFAS No. 155 is effective for all financial instruments acquired, issued or subject to a remeasurement event occurring

in fiscal years beginning after September 15, 2006. Earlier adoption is permitted, provided we have not yet issued financial statements, including for interim periods, for that fiscal year. We do not expect the adoption of SFAS No. 155 to have a material impact on our financial position, results of operations or cash flows.

**Table of Contents**

In June 2006, the FASB ratified the consensus on EITF Issue No. 06-03, *How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement.* The scope of EITF Issue No. 06-03 includes any tax assessed by a governmental authority that is directly imposed on a revenue-producing transaction between a seller and a customer and may include, but is not limited to, sales, use, value added, Universal Service Fund ( USF ) contributions and some excise taxes. The Task Force affirmed its conclusion that entities should present these taxes in the income statement on either a gross or a net basis, based on their accounting policy, which should be disclosed pursuant to APB Opinion No. 22, *Disclosure of Accounting Policies.* If such taxes are significant, and are presented on a gross basis, the amounts of those taxes should be disclosed. The consensus on Issue No. 06-03 will be effective for interim and annual reporting periods beginning after December 15, 2006. We are currently evaluating the impact of EITF No. 06-03. Should we need to change the manner in which we record gross receipts, it is not expected that the change would have a material impact on total operating revenue and expenses and operating income and net income would not be affected.

In June 2006, the FASB issued FASB Interpretation No. ( FIN ) 48, *Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109*, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006 and we will be adopting the provisions of FIN 48 beginning with the first quarter of 2007. We continue to evaluate the impact that the adoption of FIN 48 will have, if any, on our consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements.* SFAS No. 157 establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The standard applies whenever other standards require (or permit) assets or liabilities to be measured at fair value. The standard does not expand the use of fair value in any new circumstances. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. Earlier application is encouraged. We continue to evaluate the impact that the adoption of SFAS No. 157 will have, if any, on our consolidated financial statements.

In December 2006, the FASB issued FASB Staff Position ( FSP ) No. EITF 00-19-2, *Accounting for Registration Payment Arrangements.* This FSP specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No. 5, *Accounting for Contingencies.* The guidance in this FSP amends FASB Statement No. 133, *Accounting for Derivative Financial Instruments and Hedging Activities*, and No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* and FIN 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* to include scope exceptions for registration payment arrangements. This FSP is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issuance of this FSP. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of this FSP, this guidance shall be effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. We do not believe the adoption of EITF 00-19-2 will have a material impact on our consolidated financial statements.

*Recently Adopted Standards*

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs An Amendment of ARB No. 43, Chapter 4.* SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted materials (spoilage). In addition, this statement requires that allocation of fixed production overheads to the costs of conversion be based on normal capacity of production facilities. As

**Table of Contents**

required by SFAS No. 151, we adopted this new accounting standard on January 1, 2006. The adoption of SFAS No. 151 did not have a material impact on our financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123-R, *Share-Based Payment*, 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. As required by SFAS No. 123-R and the SEC, we adopted SFAS No. 123-R on January 1, 2006 (Note 15).

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections A Replacement of APB Opinion No. 20 and FASB Statement No. 3*, which replaces APB Opinion No. 20, *Accounting Changes,* and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*. The statement requires a voluntary change in accounting principle be applied retrospectively to all prior period financial statements so that those financial statements are presented as if the current accounting principle had always been applied. APB Opinion No. 20 previously required most voluntary changes in accounting principle to be recognized by including in net income of the period of change the cumulative effect of changing to the new accounting principle. In addition, SFAS No. 154 carries forward, without change, the guidance contained in APB Opinion No. 20 for reporting a correction of an error in previously issued financial statements and a change in accounting estimate. SFAS No. 154 was effective for accounting changes and corrections of errors made after January 1, 2006. The adoption of SFAS No. 154 had no impact on our financial statements.

In September 2006, the SEC issued SEC Staff Accounting Bulletin ( SAB ) No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* to provide guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. Under SAB No. 108, companies should evaluate a misstatement based on its impact on the current year income statement, as well as the cumulative effect of correcting such misstatements that existed in prior years existing in the current year s ending balance sheet. SAB No. 108 is effective for fiscal years ending after November 15, 2006. The adoption of SAB No. 108 did not have a material impact on our financial position, results of operations or cash flows.

Effective December 31, 2006, we adopted the recognition provisions of SFAS No. 158, *Employers Accounting for Defined Benefit Pension and Other Postretirement Plans An Amendment of FASB Statements No. 87, 88, 106, and 132(R).* This Statement requires employers to recognize in their balance sheets the overfunded or underfunded status of defined benefit postretirement plans, measured as the difference between the fair value of plan assets and the benefit obligation (the projected benefit obligation for pension plans and the accumulated postretirement benefit obligation for other post-retirement plans). Employers must recognize the change in the funded status of the plan in the year in which the change occurs through other comprehensive income. This Statement also requires plan assets and obligations to be measured as of the employer s balance sheet date. The measurement provision of this Statement will be effective for years beginning after December 15, 2008, with early application encouraged. We have not yet adopted the measurement provisions of this Statement and are in the process of determining the impact of the adoption on our consolidated financial statements.

Prior to the adoption of the recognition provisions of SFAS No. 158, we accounted for our defined benefit post-retirement plans under SFAS No. 87, *Employers Accounting for Pensions.* SFAS No. 87 required that a liability (minimum pension liability) be recorded when the accumulated benefit obligation liability exceeded the fair value of plan assets. Any adjustment is recorded as a non-cash charge to accumulated other comprehensive income in stockholders equity. Under SFAS No. 87, changes in the funded status were not immediately recognized, rather they were deferred and recognized ratably over future periods. Upon adoption of the recognition provisions of SFAS No. 158, we recognized the amounts of prior changes in the funded status of our postretirement benefit plans

through accumulated other comprehensive income. As a result, we

Table of Contents

recognized the following adjustments in individual line items of our consolidated balance sheet as of December 31, 2006:

| | Prior to Application of SFAS No. 158 | Effect of Adopting SFAS No. 158 | As Reported at December 31, 2006 |
|---|---|---|---|
| | | (in thousands) | |
| Deferred tax asset, current portion | $ 4,435 | $ 897 | $ 5,332 |
| Deferred tax asset, long-term | $ (29) | $ 107 | $ 78 |
| Other long-term liabilities | $ 6,043 | $ 4,487 | $ 10,530 |
| Accumulated other comprehensive income | $ 17,919 | $ (3,738) | $ 14,181 |

The adoption of SFAS No. 158 had no effect on our consolidated statement of operations for the year ended December 31, 2006, or for any prior period presented.

As of December 31, 2006, included in accumulated other comprehensive income was unrecognized prior service costs of $6.8 million and unrecognized actuarial gain of $2.3 million. The estimated prior service cost and actuarial loss that will be recognized in net periodic postretirement benefit obligation expense during 2007 is $0 million and $0.1 million, respectively.

## 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, 2006, our short-term investments approximated market value.

At December 31, 2006, we had revolving lines of credit available to us of up to $110.0 million and a term loan of $44.8 million, under our primary senior credit facility. As of December 31, 2006, no borrowings were outstanding under the line of credit. We may repay any future borrowings under the revolving lines of credit at any time but in no event later than March 31, 2008. Borrowings under the revolving lines of credit bear interest at either (i) the London Interbank Offered Rate, or LIBOR, as defined in the 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. On February 1, 2007, we paid the remaining principal balance outstanding of $44.8 million and accrued interests under our senior credit facility.

As of December 31, 2006, the LIBOR and Index rates applicable under our primary senior credit facility were 9.35% and 11%, 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

Table of Contents

borrowings under the revolving lines of credit as of December 31, 2006 over the next twelve months is quantified and summarized as follows:

| | Interest Expense Increase (in thousands) |
|---|---|
| Interest rates increase by 1 basis point | $ 448 |
| Interest rates increase by 2 basis points | $ 896 |

**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 2006, the net impact of foreign currency changes on transactions was a loss of $2.7 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.

Gross margins of products we manufacture at our European plants and sell in U.S. dollar are also affected by foreign currency exchange rate movements. Our gross margin on total net product sales was 39% in 2006. If the U.S. dollar had been stronger by 1%, 5% or 10%, compared to the actual rates during 2006, our gross margin on total net product sales would have been 39.5%, 39.8% and 40.3%, 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 2006, the U.S. dollar was stronger by:** | | |

| | | |
|---|---|---|
| 1% | $ 1,700 | $ 136 |
| 5% | $ 8,500 | $ 323 |
| 10% | $ 17,000 | $ 557 |

**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.

Table of Contents

The following table presents selected quarterly financial data for each of the quarters in the years ended December 31, 2006 and 2005:

| | 2006 | | | |
|---|---|---|---|---|
| | First Quarter(2) | Second Quarter(3) | Third Quarter(4) | Fourth Quarter(5) |
| | (in thousands, except per share data) | | | |
| Net revenue | $ 127,821 | $ 139,713 | $ 144,912 | $ 157,008 |
| Gross profit | $ 52,254 | $ 48,496 | $ 61,145 | $ 67,328 |
| Net (loss) income | $ (2,630) | $ (10,556) | $ (9,683) | $ 6,027 |
| Net (loss) income per common share basic(1) | $ (0.09) | $ (0.33) | $ (0.27) | $ 0.15 |
| Net (loss) income per common share diluted(1) | $ (0.09) | $ (0.33) | $ (0.27) | $ 0.15 |

| | 2005 | | | |
|---|---|---|---|---|
| | First Quarter(6) | Second Quarter(7) | Third Quarter(8) | Fourth Quarter(9) |
| 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 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) |

(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(m) and 13 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 2006 is a $0.9 million charge related to the closure of our manufacturing facility in Galway, Ireland, a $1.2 million unrealized foreign exchange loss associated with the closure our Galway, Ireland facility and $1.3 million of non-cash stock-based compensation expense.

(3) Included in net loss in the second quarter of 2006 is a $4.4 million restructuring charge, including $9.9 million primarily related to the closure of our ABI operation in San Diego, California, offset by income of $5.5 million related to a foreign exchange gain associated with the final closure of our manufacturing facility in Galway, Ireland, a $3.2 million net loss on disposition resulting from a $4.6 million loss associated with management s decision to dispose of our Scandinavian research operation, offset by a $1.4 million gain on the sale of an idle manufacturing facility and $1.2 million of non-cash stock-based compensation expense.

(4) Included in net loss in the third quarter of 2006 is a $5.0 million charge for the write-off of in-process research and development acquired in connection with the Clondiag acquisition, a $1.2 million restructuring charge related to the closure of our ABI operation, along with the write-off of fixed assets at other facilities impacted by our restructuring plans and $1.3 million of non-cash stock-based compensation expense.

(5)

Included in net income in the fourth quarter of 2006 is a $1.2 million restructuring charge associated with the closure of our ABI operation, a $0.3 million net loss on disposition resulting from the finalization of our disposition of our Scandinavian research operation and $1.6 million of non-cash stock-based compensation expense.

(6) 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.

(7) 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.

Table of Contents

(8) 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.

(9) 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.

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

Not applicable.

## ITEM 9A. CONTROLS AND PROCEDURES

*Management s conclusions regarding the effectiveness of our disclosure controls and procedures*

Our management evaluated, with the participation of our Chief Executive Officer (CEO) and Chief Financial Officer (CFO), the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended) as of the end of the period covered by this annual report on Form 10-K. Based on this evaluation, our management, including the CEO and CFO, concluded that our disclosure controls and procedures were effective at that time. 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, 2006. 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

Table of Contents

(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, 2006.

In conducting management s evaluation of the effectiveness of our company s internal control over financial reporting, management excluded the acquisitions which were completed in 2006. The contribution from these acquisitions represented approximately 10.0% and 5.2% of net revenue and total assets, respectively, as of and for the year ended December 31, 2006. Refer to Note 4 of the accompanying consolidated financial statements for further discussion of our 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, 2006.

Table of Contents

**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, 2006 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 Annual Report on Internal Control Over Financial Reporting, management s assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of acquisitions completed in 2006 which are included in the 2006 consolidated financial statements of Inverness Medical Innovations, Inc. and subsidiaries and constituted approximately 10.0% and 5.2% of consolidated net revenue and consolidated total assets, respectively, as of and for the year ended December 31, 2006. 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 2006. Refer to Note 4 of the accompanying 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, 2006, is fairly stated, in all material respects, is based on the criteria established in *Internal Control Integrated Framework* issued by the

Table of Contents

COSO. Also, in our opinion, Inverness Medical Innovations, Inc. and subsidiaries maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, 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 1, 2007 expressed an unqualified opinion.

/s/ BDO Seidman, LLP

Boston, MA
March 1, 2007

*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 2006 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

Not applicable.

Table of Contents

## PART III

### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information regarding directors, executive officers and corporate governance included in our definitive Proxy Statement to be filed pursuant to Regulation 14A in connection with our 2007 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, AND DIRECTOR INDEPENDENCE

The information regarding certain relationships and related transactions, and director independence 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:


| | |
|---|---|
| Report of Independent Registered Public Accounting Firm | F-2 |
| Consolidated Statements of Operations for the Years Ended December 31, 2006, 2005 and 2004 | F-3 |
| Consolidated Balance Sheets as of December 31, 2006 and 2005 | F-4 |
| Consolidated Statements of Stockholders Equity and Comprehensive Income (Loss) for the Years Ended December 31, 2006, 2005 and 2004 | F-5 |
| Consolidated Statements of Cash Flows for the Years Ended December 31, 2006, 2005 and 2004 | F-8 |
| Notes to Consolidated Financial Statements | F-11 |


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 herein.

Table of Contents

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 (incorporated by reference to Exhibit 2.7 to the Company s Annual Report on Form 10-K, as amended, for the year ended December 30, 2006) |
| 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 (incorporated by reference to Exhibit 2.9 to the Company s Annual Report on Form 10-K, as amended, for the year ended December 30, 2006) |
| *2.10 | Asset Purchase Agreement, dated December 22, 2006, by and between Inverness Medical Switzerland GmbH, Procter & Gamble International Operations, and IMJV GmbH |
| *2.11 | Contribution Agreement, dated December 22, 2006, by and between Inverness Medical Switzerland GmbH, Procter & Gamble International Operations, and IMJV GmbH |
| 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)

*3.4 Amended and Restated Certificate of Incorporation of the Company

*3.5 Certificate of Correction to Amended and Restated Certificate of Incorporation of the Company

Table of Contents

| | |
|---|---|
| 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 (incorporated by reference to Exhibit 10.6 to the Company s Annual Report on Form 10-K, as amended, for the year ended December 30, 2006) |
| 10.7 | 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) |
| +10.8 | 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) |
| 10.9 | 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)

Table of Contents

| | |
|---|---|
| 10.10 | 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) |
| 10.11 | 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) |
| 10.12 | Warrant for the Purchase of Shares of Common Stock of the Company, dated as of March 31, 2005, issued to Roger Piasio (incorporated by reference to Exhibit 10.23 to the Company s Annual Report on Form 10-K, as amended, for the year ended December 30, 2006) |
| 10.13 | 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) |
| 10.14 | 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) |
| 10.15 | 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) |
| 10.16 | 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) |
| 10.17 | 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)) |
| 10.18 | 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) |
| 10.19 | 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) |
| 10.20 | 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) |
| 10.21 | 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)

Table of Contents

| | |
|---|---|
| 10.22 | 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 (incorporated by reference to Exhibit 10.35 to the Company s Annual Report on Form 10-K, as amended, for the year ended December 30, 2006) |
| 10.23 | 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 (incorporated by reference to Exhibit 10.36 to the Company s Annual Report on Form 10-K, as amended, for the year ended December 30, 2006) |
| 10.24 | Fifth Amendment and Consent to Third Amended and Restated Credit Agreement, dated as of March 31, 2006, to the Third Amended and Restated Credit Agreement, dated as of June 30, 2005 (as amended, supplemented or otherwise modified from time to time), 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, co-syndication agent and lender, UBS Securities LLC, as 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) |
| 10.25 | Sixth Amendment and Consent to Third Amended and Restated Credit Agreement, dated as of May 3, 2006, to the Third Amended and Restated Credit Agreement, dated as of June 30, 2005 (as amended, supplemented or otherwise modified from time to time), 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, co-syndication agent and lender, UBS Securities LLC, as co-syndication agent, and the Lenders signatory thereto from time to time (incorporated by reference to Exhibit 10.1 to the Company s Quarterly Report on Form 10-Q for the period ended September 30, 2006) |
| 10.26 | Seventh Amendment and Consent to Third Amended and Restated Credit Agreement, dated as of October 6, 2006, to the Third Amended and Restated Credit Agreement, dated as of June 30, 2005 (as amended, supplemented or otherwise modified from time to time), 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, co-syndication agent and lender, UBS Securities LLC, as 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 for the period ended September 30, 2006) |
| 10.27 | Eighth Amendment and Consent to Third Amended and Restated Credit Agreement, dated as of October 30, 2006, to the Third Amended and Restated Credit Agreement, dated as of June 30, 2005 (as amended, supplemented or otherwise modified from time to time), 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, co-syndication agent and lender, UBS Securities LLC, as co-syndication agent, and the Lenders signatory thereto from time to time (incorporated by reference to Exhibit 10.3 to the Company s Quarterly Report on Form 10-Q for the period ended September 30, 2006)

Table of Contents

| | |
|---|---|
| *10.28 | Ninth Amendment and Consent to Third Amended and Restated Credit Agreement, dated as of November 10, 2006, to the Third Amended and Restated Credit Agreement, dated as of June 30, 2005 (as amended, supplemented or otherwise modified from time to time), 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, co-syndication agent and lender, UBS Securities LLC, as co-syndication agent, and the Lenders signatory thereto from time to time |
| 10.29 | 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)) |
| 10.30 | 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) |
| 10.31 | 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) |
| 10.32 | 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) |
| 10.33 | 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) |
| 10.34 | 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) |
| +10.35 | 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) |
| +10.36 | 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) |
| +10.37 | 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) |
| 10.38 | Investor Rights Agreement, dated March 31, 2006, by and among Inverness Medical Innovations, Inc., Ron Zwanziger, ACON Laboratories, Inc., AZURE Institute, Inc., LBI, Inc., Oakville Hong Kong Co., Ltd., ACON Biotech (Hangzhou) Co., Ltd., Karsson Overseas Ltd., Manfield Top Worldwide Ltd., Overseas Square Ltd., Jixun Lin and Feng Lin (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) |
| 10.39 | Second Territory Letter Agreement, dated March 31, 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., Karsson Overseas Ltd., Jixun Lin and Feng Lin (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) |
| *10.40 | |

| | |
|---|---|
| | Subunderlease, dated 15 February 2007, between the Landlord, Unilever U.K. Central Resources Limited, the Tenant, Unipath Limited, and the Surety, Inverness Medical Innovations, Inc. |
| *10.41 | Amendment No. 4 to Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan |
| *10.42 | Amendment No. 5 to Inverness Medical Innovations, Inc. 2001 Stock Option and Incentive Plan |

Table of Contents

| | |
|---|---|
| 10.43 | Underwriting Agreement dated January 25, 2007 (incorporated by reference to Exhibit 1.1 to the Company s Current Report on Form 8-K, dated January 26, 2007) |
| *14.50 | Inverness Medical Innovations Business Conduct Guidelines |
| *21.1 | List of Subsidiaries of the Company as of March 1, 2007 |
| *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.

Table of Contents

**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 1, 2007

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

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

| Signature | Title | Date |
|---|---|---|
| /s/ Ron Zwanziger<br>Ron Zwanziger | Chief Executive Officer, President and Director (Principal Executive Officer) | March 1, 2007 |
| /s/ David Teitel<br>David Teitel | Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer) | March 1, 2007 |
| /s/ Carol R. Goldberg<br>Carol R. Goldberg | Director | March 1, 2007 |
| /s/ Robert P. Khederian<br>Robert P. Khederian | Director | March 1, 2007 |
| /s/ John F. Levy<br>John F. Levy | Director | March 1, 2007 |
| /s/ Jerry McAleer<br>Jerry McAleer | Director | March 1, 2007 |
| /s/ John A. Quelch<br>John A. Quelch | Director | March 1, 2007 |
| /s/ David Scott<br>David Scott | Director | March 1 2007 |

| | | |
|---|---|---|
| /s/ Peter Townsend | Director | March 1, 2007 |
| Peter Townsend | | |
| /s/ Alfred M. Zeien | Director | March 1, 2007 |
| Alfred M. Zeien | | |

Table of Contents

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

**CONSOLIDATED FINANCIAL STATEMENTS**

**Table of Contents**


| | Page |
|---|---|
| Report of Independent Registered Public Accounting Firm | F-2 |
| Consolidated Statements of Operations for the Years Ended December 31, 2006, 2005 and 2004 | F-3 |
| Consolidated Balance Sheets as of December 31, 2006 and 2005 | F-4 |
| Consolidated Statements of Stockholders Equity and Comprehensive Income (Loss) for the Years Ended December 31, 2006, 2005 and 2004 | F-5 |
| Consolidated Statements of Cash Flows for the Years Ended December 31, 2006, 2005 and 2004 | F-8 |
| Notes to Consolidated Financial Statements | F-11 |

Table of Contents

## 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, 2006 and 2005, 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, 2006. 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, 2006 and 2005, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2006, in conformity with accounting principles generally accepted in the United States of America.

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, 2006, 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 1, 2007, 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 1, 2007

Table of Contents

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

**CONSOLIDATED STATEMENTS OF OPERATIONS**

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

| | 2006 | 2005 | 2004 |
|---|---|---|---|
| Net product sales | $ 552,130 | $ 406,457 | $ 365,432 |
| License and royalty revenue | 17,324 | 15,393 | 8,559 |
| **Net revenue** | 569,454 | 421,850 | 373,991 |
| Cost of sales | 340,231 | 269,538 | 226,987 |
| **Gross profit** | 229,223 | 152,312 | 147,004 |
| Operating expenses: | | | |
| Research and development (Note 11) | 53,666 | 30,992 | 31,954 |
| Sales and marketing | 94,445 | 72,103 | 57,957 |
| General and administrative | 71,243 | 59,990 | 52,707 |
| Loss on dispositions, net (Note 22) | 3,498 | | |
| **Operating income (loss)** | 6,371 | (10,773) | 4,386 |
| Interest expense, including amortization of original issue discounts and write-off of deferred financing costs (Note 6) | (26,570) | (21,795) | (22,114) |
| Other income (expense), net | 9,084 | 20,178 | 3,407 |
| **Loss before provision for income taxes** | (11,115) | (12,390) | (14,321) |
| Provision for income taxes | 5,727 | 6,819 | 2,275 |
| **Net loss** | $ (16,842) | $ (19,209) | $ (16,596) |
| **Net loss available to common stockholders basic and diluted (Note 13)** | $ (16,842) | $ (19,209) | $ (17,345) |
| **Net loss per common share basic (Notes 2(m) and 13)** | $ (0.49) | $ (0.79) | $ (0.87) |
| **Net loss per common share diluted (Notes 2(m) and 13)** | $ (0.49) | $ (0.79) | $ (0.87) |
| **Weighted average shares basic** | 34,109 | 24,358 | 19,969 |
| **Weighted average shares diluted** | 34,109 | 24,358 | 19,969 |

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

Table of Contents

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

**CONSOLIDATED BALANCE SHEETS**

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

| | December 31, 2006 | 2005 |
|---|---|---|
| **ASSETS** | | |
| **Current assets:** | | |
| Cash and cash equivalents | $ 71,104 | $ 34,270 |
| Accounts receivable, net of allowances of $8,401 and $9,748 at December 31, 2006 and 2005, respectively | 100,388 | 70,476 |
| Inventories, net | 78,322 | 71,209 |
| Deferred tax assets | 5,332 | 844 |
| Prepaid expenses and other current assets | 20,398 | 17,534 |
| **Total current assets** | 275,544 | 194,333 |
| Property, plant and equipment, net | 82,312 | 72,211 |
| Goodwill | 439,369 | 322,210 |
| Other intangible assets with indefinite lives | 68,107 | 63,742 |
| Core technology and patents, net | 87,732 | 64,050 |
| Other intangible assets, net | 83,794 | 60,489 |
| Deferred financing costs, net, and other non-current assets | 13,218 | 13,013 |
| Other investments and available for sale securities | 35,617 | 456 |
| Deferred tax assets | 78 | 662 |
| **Total assets** | $ 1,085,771 | $ 791,166 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | |
| **Current liabilities:** | | |
| Current portion of long-term debt | $ 7,504 | $ 2,367 |
| Current portion of capital lease obligations | 584 | 542 |
| Accounts payable | 46,342 | 42,155 |
| Accrued expenses and other current liabilities | 87,801 | 64,746 |
| **Total current liabilities** | 142,231 | 109,810 |
| **Long-term liabilities:** | | |
| Long-term debt, net of current portion | 194,473 | 258,617 |
| Capital lease obligations, net of current portion | 415 | 978 |
| Deferred tax liabilities | 23,984 | 18,881 |
| Other long-term liabilities | 10,530 | 5,572 |
| **Total long-term liabilities** | 229,402 | 284,048 |

| | | |
|---|---|---|
| **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, 2006 and 2005 | | |
| Outstanding: none at December 31, 2006 and 2005 | | |
| | | |
| **Stockholders equity:** | | |
| Preferred stock, $0.001 par value | | |
| Authorized: 2,333 shares | | |
| Issued: none | | |
| Common stock, $0.001 par value | | |
| Authorized: 100,000 shares | | |
| Issued and outstanding: 39,215 shares at December 31, 2006 and 27,497 shares at December 31, 2005 | 39 | 27 |
| Additional paid-in capital | 826,987 | 515,147 |
| Notes receivable from stockholders | | (14,691) |
| Accumulated deficit | (127,069) | (110,227) |
| Accumulated other comprehensive income | 14,181 | 7,052 |
| **Total stockholders equity** | 714,138 | 397,308 |
| **Total liabilities and stockholders equity** | $ 1,085,771 | $ 791,166 |

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

Table of Contents

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

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

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

| | Common Stock $0.001 Par Value | | Additional Paid-in Capital | Notes Receivable from Stockholders | Accumulated Deficit | Accumulated Other Comprehensive Income | Total Stockholders Equity | Comprehensive Income (Loss) |
|---|---|---|---|---|---|---|---|---|
| | Number of Shares | | | | | | | |
| 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 14(b)) | 416 | 1 | 6,933 | | (739) | | 6,195 | |
| Redemption interest related to series A redeemable convertible preferred stock (Note 14(b)) | | | | | (10) | | (10) | |
| Conversion of convertible | 346 | | 6,034 | | | | 6,034 | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| subordinated promissory notes to common stock (Note 6(d)) | | | | | | | | |
| Other (Note 16) | | | | | 33 | 33 | $ | 33 |
| Pension liability adjustment | | | | | 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.

Table of Contents

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

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE INCOME (LOSS)**
**(Continued)**
**(in thousands, except per share amounts)**

| | Common Stock $0.001 | | Additional | Notes Receivable | | Accumulated Other | Total | |
|---|---|---|---|---|---|---|---|---|
| | Number of Shares | Par Value | Paid-in Capital | From Stockholders | Accumulated Deficit | Comprehensive Income | Stockholders Equity | Comprehensive Loss |
| 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.

Table of Contents

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

**CONSOLIDATED STATEMENTS OF STOCKHOLDERS EQUITY AND COMPREHENSIVE INCOME (LOSS)**
**(Continued)**
**(in thousands, except per share amounts)**

| | Common Stock $0.001 Par Value | | Additional Paid-in Capital | Notes Receivable From Stockholders | Accumulated Deficit | Accumulated Other Comprehensive Income | Total Stockholders Equity | Comprehensive Income (Loss) |
|---|---|---|---|---|---|---|---|---|
| | Number of Shares | | | | | | | |
| BALANCE, DECEMBER 31, 2005 | 27,497 | $ 27 | $ 515,147 | $ (14,691) | $ (110,227) | $ 7,052 | $ 397,308 | |
| Issuance of common stock in connection with acquisitions and equity offering, net of issuance costs of $9,617 | 10,893 | 11 | 295,488 | | | | 295,499 | |
| Exercise of common stock options and warrants and shares issued under employee stock purchase plan | 825 | 1 | 10,330 | | | | 10,331 | |
| Stock-based compensation related to grants of common stock options | | | 5,455 | | | | 5,455 | |
| Stock option income tax benefits | | | 567 | | | | 567 | |
| Repayment of notes receivable from stockholder options | | | | 14,691 | | | 14,691 | |
| Pension liability adjustment | | | | | | (3,738) | (3,738) | $ (3,738) |
| | | | | | | 10,823 | 10,823 | 10,823 |

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| Changes in cumulative translation adjustment | | | | | | | | | | |
| Unrealized gain on available-for-sale securities | | | | | | | 44 | 44 | | 44 |
| Net loss | | | | | | (16,842) | | (16,842) | | (16,842) |
| Total comprehensive loss | | | | | | | | | $ | (9,713) |
| BALANCE, DECEMBER 31, 2006 | 39,215 | $ 39 | $ 826,987 | $ | $ | (127,069) | $ 14,181 | $ 714,138 | | |

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

Table of Contents

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**
**CONSOLIDATED STATEMENTS OF CASH FLOWS**
**(in thousands)**

| | 2006 | 2005 | 2004 |
|---|---|---|---|
| **Cash Flows from Operating Activities:** | | | |
| Net loss | $ (16,842) | $ (19,209) | $ (16,596) |
| Adjustments to reconcile net loss to net cash provided by operating activities: | | | |
| Interest expense related to amortization and write-off of non-cash original issue discount, non-cash beneficial conversion feature and deferred financing costs | 4,158 | 2,345 | 4,929 |
| Non-cash loss (income) related to currency hedge and interest rate swap agreements | (217) | 217 | (695) |
| Non-cash stock-based compensation expense | 5,455 | 169 | |
| Charge for in-process research and development | 4,960 | | |
| Non-cash value on settlement of litigation | | (2,593) | (495) |
| Impairment of long-lived assets | 9,573 | 1,740 | |
| (Gain) loss on sale of fixed assets | (1,528) | 263 | |
| Interest in minority investments | (635) | | |
| Depreciation and amortization | 39,362 | 27,756 | 23,500 |
| Deferred income taxes | (409) | 5,969 | 2,232 |
| Other non-cash items | 714 | 141 | (36) |
| Changes in assets and liabilities, net of acquisitions: | | | |
| Accounts receivable, net | (13,846) | 10,404 | (4,095) |
| Inventories, net | 167 | (4,047) | (11,073) |
| Prepaid expenses and other current assets | (86) | (7,598) | 2,116 |
| Accounts payable | 210 | 6,201 | (6,897) |
| Accrued expenses and other current liabilities | 3,294 | 4,496 | 15,049 |
| Other non-current liabilities | (60) | 339 | 356 |
| **Net cash provided by operating activities** | 34,270 | 26,593 | 8,295 |
| **Cash Flows from Investing Activities:** | | | |
| Purchases of property, plant and equipment | (19,717) | (20,233) | (20,389) |
| Proceeds from sale of property, plant and equipment | 2,244 | 241 | 385 |
| Cash paid for purchase of Ischemia Technologies, Inc., net of cash acquired | (99) | (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 | (237) | (20,030) | |
| Cash paid for purchase of CLONDIAG chip technologies Gmbh, net of cash acquired | (17,576) | | |
| Cash paid for purchase of ABON BioPharm (Hangzhou) Co. Ltd. and ACON Laboratories, net of cash acquired | (112,643) | | |

| | | | |
|---|---|---|---|
| Cash paid for purchase of other businesses and intellectual property | (910) | (5,175) | (12,409) |
| Cash paid for investments in minority interests and available-for-sale securities | (25,817) | | |
| Decrease in other assets | (4,077) | (1,787) | (1,889) |
| **Net cash used in investing activities** | (178,832) | (170,761) | (34,302) |
| **Cash Flows from Financing Activities:** | | | |
| Cash paid for financing costs | (2,787) | (2,873) | (5,671) |
| Proceeds from issuance of common stock, net of issuance costs | 234,961 | 97,440 | 1,905 |
| Net (payments) proceeds under revolving line of credit | (47,879) | 69,442 | (30,830) |
| Stock-based compensation excess tax benefit | 567 | | |
| Proceeds from issuance of senior subordinated notes | | | 150,000 |
| Proceeds from borrowings under notes payable | | 269 | |
| Repayments of notes payable | (20,000) | | (97,830) |
| Repayments of notes receivable | 14,691 | | |
| Principal payments of capital lease obligations | (546) | (501) | (477) |
| **Net cash provided by financing activities** | 179,007 | 163,777 | 17,097 |
| Foreign exchange effect on cash and cash equivalents | 2,389 | (2,095) | 1,044 |
| Net increase (decrease) in cash and cash equivalents | 36,834 | 17,514 | (7,866) |
| Cash and cash equivalents, beginning of year | 34,270 | 16,756 | 24,622 |
| **Cash and cash equivalents, end of year** | $ 71,104 | $ 34,270 | $ 16,756 |
| **Supplemental Disclosure of Cash Flow Information:** | | | |
| Interest paid | $ 22,686 | $ 19,268 | $ 13,535 |
| Taxes paid | $ 8,841 | $ 4,106 | $ 3,067 |

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

Table of Contents

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

| | 2006 | 2005 | 2004 |
|---|---|---|---|
| **Supplemental Disclosure of Non-cash Activities:** | | | |
| On May 15, 2006, we acquired ABON BioPharm (Hangzhou) Co. Ltd. and ACON Laboratories (Note 4(a)) | | | |
| Accounts receivable | $ 11,328 | $ | $ |
| Inventories | 4,814 | | |
| Property, plant and equipment | 10,274 | | |
| Other assets | 1,369 | | |
| Intangible assets | 160,116 | | |
| Accounts payable and accrued expenses | (4,081) | | |
| Other liabilities | (18,125) | | |
| Cash paid for purchase of ABON BioPharm (Hangzhou) Co. Ltd. and ACON Laboratories, net of cash acquired | (112,643) | | |
| Fair value of common stock issued | $ 53,052 | $ | $ |
| On February 28, 2006, we acquired CLONDIAG chip technologies Gmbh (Note 4(a)) | | | |
| Accounts receivable | $ 295 | $ | $ |
| Inventories | 90 | | |
| Property, plant and equipment | 1,790 | | |
| Other assets | 556 | | |
| Intangible assets | 22,901 | | |
| Accounts payable and accrued expenses | (1,581) | | |
| Cash paid for purchase of CLONDIAG chip technologies Gmbh, net of cash acquired | (17,576) | | |
| Fair value of common stock issued | $ 6,475 | $ | $ |
| On September 30, 2005, we acquired Thermo BioStar, Inc. (Note 4(b)) | | | |
| 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(b)) | | | |
| Accounts receivable | $ | $ 10,913 | $ |
| Inventories | | 520 | |
| Property, plant and equipment | | 771 | |
| Prepaid expenses and Other assets | | 188 | |
| Intangible assets | | 12,062 | |
| Accrued acquisition costs | 237 | (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 | $ (237) | (20,030) | |
| | $ | $ | $ |
| On June 30, 2005, we acquired the Determine business from Abbott Laboratories (Note 4(b)) | | | |
| Inventories | $ | $ 3,412 | $ |
| Property, plant and equipment | | 1,500 | |
| Intangible assets | | 56,913 | |
| Accounts payable and Accrued expenses | | (3,723) | |
| Cash paid for purchase of the Determine business | | (58,102) | |
| | $ | $ | $ |

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

Table of Contents

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

| | 2006 | 2005 | 2004 |
|---|---|---|---|
| On March 31, 2005, we acquired Binax, Inc. (Note 4(b)) | | | |
| Accounts receivable | $ | $ 5,264 | $ |
| Inventories | | 3,086 | |
| Property, plant and equipment | | 2,421 | |
| Prepaid expenses and 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 | $ |
| On March 16, 2005, we acquired Ischemia Technologies, Inc. (Note 4(b)) | | | |
| Accounts receivable | $ | $ 58 | $ |
| Inventories | | 40 | |
| Property, plant and equipment | | 288 | |
| Intangible assets | | 26,932 | |
| Other assets | | 99 | |
| Assumed liabilities | | (50) | |
| Accrued acquisition costs | 99 | (144) | |
| Accounts payable and accrued expenses | | (377) | |
| Cash paid for purchase of Ischemia Technologies, Inc., net of cash acquired | (99) | (4,096) | |
| Fair value of common stock issued | $ | $ 22,750 | $ |
| During 2006, 2005, 2004, 2003 and 2002, we acquired other businesses and intellectual property | | | |
| Accounts receivable | $ | $ | $ 496 |
| Inventories | 455 | | 875 |
| Property, plant and equipment | 3 | | (903) |
| Intangible assets | 346 | 4,971 | 14,493 |
| Prepaid expenses and other assets | | | 170 |
| Accounts payable and accrued expenses | (3) | | (2,827) |
| Accrued acquisition costs | 109 | 204 | 3,553 |
| Net deferred tax liabilities | | | (446) |
| Cash paid for purchase of other businesses and intellectual property | (910) | (5,175) | (12,409) |
| Fair value of common stock issued | $ | $ | $ 3,002 |
| Dividends, interest and amortization of beneficial conversion feature related to preferred stock (Notes 13 and 14(b)) | $ | $ | $ 749 |

| | | | |
|---|---|---|---|
| Conversion of preferred stock to common stock (Note 14(b)) | $ | $ | $ 6,934 |
| Conversion of subordinated notes to common stock | $ | $ | $ 6,034 |

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

Table of Contents

**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.

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 acquired businesses that were in excess of the fair value of net assets acquired and the resultant goodwill (Note 4).

In December 2006, we signed a definitive agreement with The Procter & Gamble Company ( P&G ) to form a 50/50 joint venture for the development, acquisition, manufacturing, marketing and sale of existing and to-be-developed consumer diagnostic products outside of the fields of cardiology and diabetes. Following the completion of the transaction, we will contribute our related consumer diagnostic and monitoring assets, other than manufacturing and core intellectual property assets, to a new joint venture entity, and P&G will acquire its interest in the joint venture in consideration for a cash payment of $325.0 million. P&G will retain an option to require us to purchase its interest in the venture back at fair market value during the 60-day period beginning on the fourth anniversary of the closing. Our primary role in the collaboration will be to develop and manufacture consumer diagnostic products while P&G s primary role will be to market, sell, and distribute existing and to-be-developed products. We will retain all rights with respect to the development and sale of cardiology diagnostic products and its professional point-of-care diagnostic businesses.

Following the completion of the transaction and the formation of the joint venture, we will cease to consolidate the operating results of our consumer diagnostics business, which represented $171.6 million of net product revenue in 2006, and instead will account for our 50% interest in the results of the joint venture under the equity method. In our capacity as the manufacturer of products for the joint venture, we will supply product to the joint venture and will record revenue on those sales. No gain on the proceeds that we receive from P&G through the formation of the joint venture will be recognized in our financial statements until P&G s option to require us to purchase its interest in the joint venture at market value expires after the fourth anniversary of the closing.

The transaction is expected to close in the first half of 2007, subject to the satisfaction of customary closing and other conditions, such as that there be no material adverse change in our consumer diagnostics business, that the transaction be permitted under the indenture governing our senior subordinated notes or that we repay all of our outstanding senior subordinated notes and that we receive favorable tax rulings from the Swiss tax authorities, the receipt of regulatory approvals, and obtaining certain third-party consents to the

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

transaction. There can be no assurance that all of these conditions will be satisfied. If these conditions are not satisfied or waived, we may be unable to complete the joint venture.

The consolidated financial statements include the accounts of Inverness Medical Innovations, Inc. and its subsidiaries. Intercompany transactions and balances are eliminated and net earnings are reduced by the portion of the net earnings of subsidiaries applicable to minority interests. Equity investments in which we exercise significant influence but do not control and are not the primary beneficiary are accounted for using the equity method. Investments in which we are not able to exercise significant influence over the investee and which do not have readily determinable fair values are accounted for under the cost method. Certain amounts for prior periods have been reclassified to conform to the current period classification.

**(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 14).

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 gains of $2.6 million during 2006, and losses of $0.3 million and $0.7 million during 2005 and 2004, respectively, are included as a component of other income, net, in the accompanying consolidated statements of operations.

*(c) Cash and Cash Equivalents*

We consider all highly liquid investments purchased with original maturities of three months or less at the date of acquisition to be cash equivalents. Cash equivalents consisted of money market funds at December 31, 2006 and 2005.

*(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.

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

*(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 3-11 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 3-15 years. Land is not depreciated. Depreciation expense related to property, plant and equipment amounted to $17.6 million, $14.9 million and $13.1 million in 2006, 2005 and 2004, respectively. Expenditures for repairs and maintenance are expensed as incurred.

*(f) Investment in Available-for-sale Securities*

Available-for-sale securities include publicly-traded equity investments which are classified as available-for-sale and recorded at fair value using the specific identification method. Unrealized gains and losses (except for other than temporary impairments) are recorded in other comprehensive income (loss), which is reported as a component of stockholders equity. We evaluate our investments on a quarterly basis to determine if a potential other than temporary impairment exists. Our evaluation considers the investees specific business conditions, as well as general industry and market conditions.

*(g) Goodwill*

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, 2006 did not indicate that goodwill related to our consumer diagnostic products or to our professional diagnostic products reporting units was impaired.

*(h) 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, 2006.

*(i) Business Acquisitions*

We account for our acquisitions using the purchase method of accounting as defined under SFAS No. 141, *Business Combinations.* Accordingly, the operating results of the acquired company is included in our consolidated financial statements of operations after the acquisition date as part of reporting unit it relates to. Accounting for these acquisitions has resulted in the capitalization of the cost in excess of fair value of the net assets acquired in each of these acquisitions as goodwill. We estimated the fair values of the assets acquired in each acquisition as of the date of acquisition and these estimates are subject to adjustment. We complete these

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

assessments within one year of the date of acquisition. We have undertaken certain restructurings of the acquired businesses to realize efficiencies and potential cost savings. Our restructuring activities include the elimination of duplicate facilities, reductions in staffing levels, and other costs associated with exiting certain activities of the businesses we acquire. The estimated cost of these restructuring activities are included as costs of the acquisition and are recorded as additional purchase price consistent with the guidance of Emerging Issue Task Force ( EITF ) Issue No. 95-3, *Recognition of Liabilities in Connection with a Purchase Business Combination.* Any common stock issued with our acquisitions is determined based on the average market price of our common stock pursuant to Issue No. 99-12, *Determination of the Measurement Date for the Market Price of Acquirer Securities Issued in a Purchase Business Combination.*

*(j) 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 17).

*(k) 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 or is estimable. In connection with the acquisitions of the Abbott rapid diagnostic business in September 2003 and the Determine/Daina Screen assets ( the Determine business) in June 2005 (Note 4(b)) from Abbott Laboratories, 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, which ended in 2006, we recognized revenue on sales of the products when title transferred from Abbott to third-party customers.

Deferred revenue is recorded when payments are received in advance of performing our service obligations and is recognized ratably over the service period. Amounts related to deferred revenue are included in Accrued expenses and other current liabilities on our consolidated balance sheet.

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.

*(l) Employee Stock-Based Compensation Arrangements*

Effective January 1, 2006, we began recording compensation expense associated with stock options and other forms of equity compensation in accordance with SFAS No. 123-R, *Share-Based Payment*, as interpreted by SEC Staff Accounting Bulletin ( SAB ) No. 107. Prior to January 1, 2006, we accounted for stock options according to the provisions of Accounting Principles Board ( APB ) Opinion No. 25, *Accounting for Stock Issued to Employees,* and related interpretations, and therefore no related compensation expense was recorded

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

for awards granted with no intrinsic value. We adopted the modified prospective transition method provided for under SFAS No. 123-R, and consequently have not retroactively adjusted results from prior periods. Under this transition method, compensation cost associated with stock options now includes: (i) amortization related to the remaining unvested portion of all stock option awards granted prior to January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123, and (ii) amortization related to all stock option awards granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123-R. In addition, we record expense over the offering period in connection with shares issued under our employee stock purchase plan. The compensation expense for stock-based compensation awards includes an estimate for forfeitures and is recognized over the expected term of the options using the straight-line method.

For stock options granted prior to the adoption of SFAS No. 123-R, if expense for stock-based compensation had been determined under the fair value method of the original SFAS 123 for the year ended December 31, 2005 and 2004, our net loss per common share would have been adjusted to the following pro forma amounts:

| | 2005 | 2004 |
|---|---|---|
| | (in thousands, except for per share data) | |
| Net loss as reported | $ (19,209) | $ (16,596) |
| Stock-based employee compensation as reported | 139 | |
| Pro forma stock-based employee compensation | (6,366) | (5,675) |
| Net loss pro forma | $ (25,436) | $ (22,271) |
| **Net loss per common share basic** | | |
| Net loss as reported | $ (0.79) | $ (0.87) |
| Stock-based employee compensation as reported | 0.01 | |
| Pro forma stock-based employee compensation | (0.26) | (0.28) |
| Net loss per common share pro forma | $ (1.04) | $ (1.15) |
| **Net loss per common share diluted** | | |
| Net loss as reported | $ (0.79) | $ (0.87) |
| Stock-based employee compensation as reported | 0.01 | |
| Pro forma stock-based employee compensation | (0.26) | (0.28) |
| Net loss per common share pro forma | $ (1.04) | $ (1.15) |

Our stock option plans provide for grants of options to employees to purchase common stock at the fair market value of such shares on the grant date of the award. The options typically vest over a four year period, beginning on the date of grant, with a graded vesting schedule of 25% at the end of each of the four years. The fair value of each option

grant is estimated on the date of grant using the Black-Scholes option-pricing method. We use historical data to estimate the expected price volatility and the expected forfeiture rate. For the year ended December 31, 2006, we have chosen to employ the simplified method of calculating the expected option term, which averages an award s weighted average vesting period and its contractual term. The contractual term of our stock option awards is ten years. The risk-free rate is based on the U.S. Treasury yield curve in effect at the time of grant with a remaining term equal to the expected term of the option. We have not made any dividend payments nor do we have plans to pay dividends in the foreseeable future.

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

*(m) 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 13).

*(n) Other Operating Expenses*

We expense advertising costs as incurred. In 2006, 2005 and 2004, advertising costs amounted to $23.0 million, $21.7 million and $19.9 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.

*(o) 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, 2006 and 2005 that were in excess of 10% of the gross accounts receivable balance on those dates. During 2006, no customers represented greater than 10% of our net revenues. During 2005 and 2004, we had one customer that represented 10% and 11%, respectively, of our net revenues, and purchased 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.

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

Our primary financial instruments at December 31, 2006 and 2005 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, 2006 and 2005. 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, 2006, we had no outstanding foreign currency exchange forward contracts. Changes of $0.2 million in the market value of these contracts during 2006 were recorded to other income (expense), net in our consolidated statements of operations.

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

*(q) Recent Accounting Pronouncements*

Recently Issued Standards

In February 2006, the Financial Accounting Standards Board ( FASB ) issued SFAS No. 155, *Accounting for Certain Hybrid Financial Instruments*, which amends SFAS No. 133, *Accounting for Derivative Instruments and Hedging Activities* and SFAS No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities.* SFAS No. 155 simplifies the accounting for certain derivatives embedded in other financial instruments by allowing them to be accounted for as a whole if the holder elects to account for the whole instrument on a fair value basis. SFAS No. 155 also clarifies and amends certain other provisions of SFAS No. 133 and SFAS No. 140. SFAS No. 155 is effective for all financial instruments acquired, issued or subject to a remeasurement event occurring in fiscal years beginning after September 15, 2006. Earlier adoption is permitted, provided we have not yet issued financial statements, including for interim periods, for that fiscal year. We do not expect the adoption of SFAS No. 155 to have a material impact on our financial position, results of operations or cash flows.

In June 2006, the FASB ratified the consensus on EITF Issue No. 06-03, *How Taxes Collected from Customers and Remitted to Governmental Authorities Should Be Presented in the Income Statement.* The scope of EITF Issue No. 06-03 includes any tax assessed by a governmental authority that is directly imposed on a revenue-producing transaction between a seller and a customer and may include, but is not limited to, sales, use, value added, Universal Service Fund ( USF ) contributions and some excise taxes. The Task Force affirmed its conclusion that entities should present these taxes in the income statement on either a gross or a net basis, based on their accounting policy, which should be disclosed pursuant to APB Opinion No. 22, *Disclosure of Accounting Policies.* If such taxes are significant, and are presented on a gross basis, the amounts of those taxes should be disclosed. The consensus on Issue No. 06-03 will be effective for interim and annual reporting periods beginning after December 15, 2006. We are currently evaluating the impact of EITF No. 06-03. Should we need to change the manner in which we record gross receipts, it is not expected that the change would have a material impact on total operating revenue and expenses and operating income and net income would not be affected.

In June 2006, the FASB issued FASB Interpretation No. ( FIN ) 48, *Accounting for Uncertainty in Income Taxes An Interpretation of FASB Statement No. 109*, which prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. FIN 48 is effective for fiscal years beginning after December 15, 2006 and we will be adopting the provisions of FIN 48 beginning with the first quarter of 2007. We continue to evaluate the impact that the adoption of FIN 48 will have, if any, on our consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements.* SFAS No. 157 establishes a framework for measuring fair value in generally accepted accounting principles, and expands disclosures about fair value measurements. The standard applies whenever other standards require (or permit) assets or liabilities to be measured at fair value. The standard does not expand the use of fair value in any new circumstances. SFAS No. 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. Earlier application is encouraged. We continue to evaluate the impact that the adoption of SFAS No. 157 will have, if any, on our consolidated financial statements.

In December 2006, the FASB issued FASB Staff Position ( FSP ) No. EITF 00-19-2, *Accounting for Registration Payment Arrangements.* This FSP specifies that the contingent obligation to make future payments or otherwise transfer consideration under a registration payment arrangement, whether issued as

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

separate agreement or included as a provision of a financial instrument or other agreement, should be separately recognized and measured in accordance with FASB Statement No. 5, *Accounting for Contingencies.* The guidance in this FSP amends FASB Statement No. 133, *Accounting for Derivative Financial Instruments and Hedging Activities*, and No. 150, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity* and FIN 45, *Guarantor s Accounting and Disclosure Requirements for Guarantees, Including Indirect Guarantees of Indebtedness of Others* to include scope exceptions for registration payment arrangements. This FSP is effective immediately for registration payment arrangements and the financial instruments subject to those arrangements that are entered into or modified subsequent to the date of issuance of this FSP. For registration payment arrangements and financial instruments subject to those arrangements that were entered into prior to the issuance of this FSP, this guidance shall be effective for financial statements issued for fiscal years beginning after December 15, 2006, and interim periods within those fiscal years. We do not believe the adoption of EITF 00-19-2 will have a material impact on our consolidated financial statements.

Recently Adopted Standards

In November 2004, the FASB issued SFAS No. 151, *Inventory Costs An Amendment of ARB No. 43, Chapter 4.* SFAS No. 151 clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs and wasted materials (spoilage). In addition, this statement requires that allocation of fixed production overheads to the costs of conversion be based on normal capacity of production facilities. As required by SFAS No. 151, we adopted this new accounting standard on January 1, 2006. The adoption of SFAS No. 151 did not have a material impact on our financial position, results of operations or cash flows.

In December 2004, the FASB issued SFAS No. 123-R, *Share-Based Payment*, 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. As required by SFAS No. 123-R and the Securities and Exchange Commission ( SEC ), we adopted SFAS No. 123-R on January 1, 2006 (Note 15).

In May 2005, the FASB issued SFAS No. 154, *Accounting Changes and Error Corrections A Replacement of APB Opinion No. 20 and FASB Statement No. 3*, which replaces APB Opinion No. 20, *Accounting Changes,* and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*. The statement requires a voluntary change in accounting principle be applied retrospectively to all prior period financial statements so that those financial statements are presented as if the current accounting principle had always been applied. APB Opinion No. 20 previously required most voluntary changes in accounting principle to be recognized by including in net income of the period of change the cumulative effect of changing to the new accounting principle. In addition, SFAS No. 154 carries forward, without change, the guidance contained in APB Opinion No. 20 for reporting a correction of an error in previously issued financial statements and a change in accounting estimate. SFAS No. 154 was effective for accounting changes and corrections of errors made after January 1, 2006. The adoption of SFAS No. 154 had no impact on our financial statements.

In September 2006, the SEC issued SAB No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements* to provide guidance on the consideration of the effects of prior year misstatements in quantifying current year misstatements for the purpose of a materiality assessment. Under SAB No. 108, companies should evaluate a misstatement based on its impact on the current year

income statement, as well as the cumulative effect of correcting such misstatements that existed in prior years existing in the current year s ending balance sheet. SAB No. 108 is effective for fiscal years ending after November 15, 2006. The adoption of SAB No. 108 did not have a material impact on our financial position, results of operations or cash flows.

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

Effective December 31, 2006, we adopted the recognition provisions of SFAS No. 158, *Employers Accounting for Defined Benefit Pension and Other Postretirement Plans An Amendment of FASB Statements No. 87, 88, 106, and 132(R).* This Statement requires employers to recognize in their balance sheets the overfunded or underfunded status of defined benefit postretirement plans, measured as the difference between the fair value of plan assets and the benefit obligation (the projected benefit obligation for pension plans and the accumulated postretirement benefit obligation for other post-retirement plans). Employers must recognize the change in the funded status of the plan in the year in which the change occurs through other comprehensive income. This Statement also requires plan assets and obligations to be measured as of the employer s balance sheet date. The measurement provision of this Statement will be effective for years beginning after December 15, 2008, with early application encouraged. We have not yet adopted the measurement provisions of this Statement and are in the process of determining the impact of the adoption on our consolidated financial statements.

Prior to the adoption of the recognition provisions of SFAS No. 158, we accounted for our defined benefit post-retirement plans under SFAS No. 87, *Employers Accounting for Pensions.* SFAS No. 87 required that a liability (minimum pension liability) be recorded when the accumulated benefit obligation liability exceeded the fair value of plan assets. Any adjustment is recorded as a non-cash charge to accumulated other comprehensive income in stockholders equity. Under SFAS No. 87, changes in the funded status were not immediately recognized, rather they were deferred and recognized ratably over future periods. Upon adoption of the recognition provisions of SFAS No. 158, we recognized the amounts of prior changes in the funded status of our postretirement benefit plans through accumulated other comprehensive income. As a result, we recognized the following adjustments in individual line items of our consolidated balance sheet as of December 31, 2006:

| | Prior to Application of SFAS No. 158 | Effect of Adopting SFAS No. 158 | As Reported at December 31, 2006 |
|---|---|---|---|
| | | (in thousands) | |
| Deferred tax asset, current portion | $ 4,435 | $ 897 | $ 5,332 |
| Deferred tax asset, long-term | $ (29) | $ 107 | $ 78 |
| Other long-term liabilities | $ 6,043 | $ 4,487 | $ 10,530 |
| Accumulated other comprehensive income | $ 17,919 | $ (3,738) | $ 14,181 |

The adoption of SFAS No. 158 had no effect on our consolidated statement of operations for the year ended December 31, 2006, or for any prior period presented.

As of December 31, 2006, included in accumulated other comprehensive income was unrecognized prior service costs of $6.8 million and unrecognized actuarial gain of $2.3 million. The estimated prior service cost and actuarial loss that will be recognized in net periodic postretirement benefit obligation expense during 2007 is $0 million and

$0.1 million, respectively.

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(3) Other Balance Sheet Information**

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

| | December 31, | |
|---|---|---|
| | 2006 | 2005 |
| | (in thousands) | |
| **Inventories, net:** | | |
| Raw materials | $ 29,372 | $ 25,488 |
| Work-in-process | 19,080 | 17,812 |
| Finished goods | 29,870 | 27,909 |
| | $ 78,322 | $ 71,209 |
| **Property, plant and equipment, net:** | | |
| Machinery, laboratory equipment and tooling | $ 81,198 | $ 78,559 |
| Land and buildings | 18,582 | 8,942 |
| Leasehold improvements | 20,870 | 18,980 |
| Computer software and equipment | 11,063 | 8,811 |
| Furniture and fixtures | 4,515 | 3,982 |
| | 136,228 | 119,274 |
| Less: Accumulated depreciation and amortization | (53,916) | (47,063) |
| | $ 82,312 | $ 72,211 |
| **Accrued expenses and other current liabilities:** | | |
| Compensation and compensation-related | $ 13,395 | $ 8,959 |
| Advertising and marketing | 9,743 | 6,608 |
| Professional fees | 5,291 | 5,649 |
| Interest payable | 6,234 | 6,002 |
| Royalty obligations | 4,923 | 4,001 |
| Deferred revenue | 6,685 | 5,981 |
| Taxes payable | 8,864 | 6,023 |
| Acquisition related obligations | 17,655 | 2,200 |
| Other | 15,011 | 19,323 |
| | $ 87,801 | $ 64,746 |

**(4) Business Combinations**

*(a) Significant Acquisitions in 2006*

(i) Acquisition of the Innovacon business, including the ABON Facility

On March 31, 2006, we acquired the assets of ACON Laboratories 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 ( the Innovacon business ). The preliminary aggregate purchase price was approximately $93.9 million which consisted of $55.1 million in cash, 711,676 shares of our common stock with an aggregate fair value of $19.7 million, $9.1 million in estimated

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

direct acquisition costs and an additional liability of $10.0 million payable to the sellers on the deferred payment date, pursuant to the purchase agreement.

On May 15, 2006, as part of the Innovacon business we acquired a newly-constructed manufacturing facility in Hangzhou, China pursuant to the terms of our acquisition agreement with ACON Laboratories, Inc. and its affiliates. In connection with the acquisition of the new facility, we acquired ABON BioPharm (Hangzhou) Co., Ltd ( ABON ), the direct owner of the new factory and now our subsidiary. The preliminary aggregate purchase price was approximately $20.8 million which consisted of $8.8 million in cash and 417,446 shares of our common stock with an aggregate fair value of $12.0 million. In addition, pursuant to the acquisition agreement, we made an additional payment of $4.1 million in cash as a result of the amount of cash acquired, net of indebtedness assumed, which increased the preliminary aggregate purchase price to $24.9 million.

Subsequent, between August and November 2006, we made cash payments totaling $44.0 million and issued 742,128 shares of our common stock with an aggregate fair value of $21.3 million as various milestones were achieved. This brings the aggregate purchase price for the Innovacon business, including the ABON facility to a total of $184.1 million.

The aggregate purchase price for the Innovacon business, including the ABON facility discussed above, was allocated to the assets acquired and liabilities assumed at the date of acquisition as follows:

| | (in thousands) |
|---|---|
| Cash | $ 8,403 |
| Accounts receivable | 11,328 |
| Inventories | 4,814 |
| Property, plant and equipment, net | 10,274 |
| Goodwill | 112,116 |
| Trademarks | 800 |
| Customer relationships | 27,700 |
| Supply agreements | 3,300 |
| Core technology | 16,200 |
| Other assets | 1,369 |
| Accounts payable and accrued expenses | (4,081) |
| Long-term debt | (8,125) |
| | $ 184,098 |

Goodwill generated from this acquisition is not deductible for tax purposes. We estimate the useful lives of the trademarks, customer relationships, supply agreements and product technology to be 10 years, 16.8 years and 17.8 years, 1.8 years and 7 years, respectively, 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 12.7 years.

The operating results of the Innovacon business are included in our consumer and professional diagnostic products reporting units and business segments.

Additionally, in connection with the acquisition of the Innovacon business, we entered into an agreement for the purchase of Acon Laboratories lateral flow immunoassay sales and distribution business in all territories not included within the territories acquired in connection with our March 31, 2006 acquisition

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

described above. Under the terms of this agreement, in the event that this business achieves a specified level of profitability, we will acquire this business in 2009 for a formulaic price based on the revenues and earnings of the business. Alternatively, we may elect not to complete the acquisition of the business in exchange for a payment equal to 15% of the purchase price that would have been due had we elected to complete the acquisition.

(ii) Acquisition of Clondiag

On February 28, 2006, we acquired 67.45% of CLONDIAG chip technologies GmbH ( Clondiag ), a privately-held company located in Jena in Germany which is developing a multiplexing technology for nucleic acid and immunoassay-based diagnostics. Pursuant to the acquisition agreement, we purchased the remaining 32.55% on August 31, 2006. The aggregate purchase price was $23.1 million, which consisted of an initial cash payment of $11.9 million, 218,502 shares of our common stock with an aggregate fair value of $5.8 million, a $5.3 million cash payment to acquire the remaining 32.55% stock ownership and $0.1 million in direct acquisition costs. Additionally, pursuant to the terms of the acquisition agreement, we have an obligation to settle existing employee bonus arrangements with the Clondiag employees totaling 1.1 million ($1.3 million). In connection with this obligation, we issued 24,896 shares of our common stock with a fair value of $0.7 million to the employees of Clondiag and a cash payment of $0.5 million. As of December 31, 2006, our remaining obligation was $0.1 million. This obligation increased our aggregate purchase price to $24.4 million as of December 31, 2006 and resulted in additional goodwill.

In addition, the terms of the acquisition agreement provide for $8.9 million of contingent consideration, 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 acquisition date. This contingent consideration will be accounted for as an increase in the aggregate purchase price if and when the contingency occurs.

The aggregate purchase price was allocated to the assets acquired and liabilities assumed at the date of acquisition as follows:

| | | (in thousands) |
|---|---|---|
| Cash and cash equivalents | $ | 270 |
| Accounts receivable | | 295 |
| Inventories | | 90 |
| Prepaid expenses and other current assets | | 536 |
| Property, plant and equipment | | 1,790 |
| Goodwill | | 6,631 |
| Patents | | 11,310 |
| In-process research and development | | 4,960 |
| Other assets | | 20 |
| Accounts payable and accrued expenses | | (1,517) |
| | $ | 24,385 |

We estimate the useful lives of the acquired patents to be 20 years and have included them in core technology and patents, net, in the accompanying consolidated balance sheet. We have also evaluated certain in-process research and development projects and have expensed, as in-process research and development, those projects that have not yet attained technical feasibility. The amount expensed during the year ended

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

December 31, 2006 was $5.0 million, and is included in research and development expense in our consolidated statement of operations.

The operating expenses of Clondiag, which consist principally of research and development activities, have been included in our corporate and other business segment. Goodwill generated from this acquisition is not deductible for tax purposes.

*(b) Significant Acquisitions in 2005*

(i) Acquisition of BioStar

On September 30, 2005, we acquired Thermo BioStar, Inc. ( 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.

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 | | 1,911 |
| Property, plant and equipment | | 1,695 |
| Goodwill | | 30,836 |
| Core technology | | 4,550 |
| Customer relationships | | 6,760 |
| Trade name | | 2,730 |
| Trademarks | | 4,200 |
| Other assets | | 745 |
| Accounts payable and accrued expenses | | (5,023) |
| | $ | 53,651 |

Goodwill generated from this acquisition is fully deductible for tax purposes over 15 years. The values allocated to the acquired core technology, customer relationships and trade name 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 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.

The operating results of BioStar have been included in our professional diagnostic products reporting unit.

(ii) Acquisition of IDT

On September 30, 2005, we acquired Innogenetics Diagnostica Y Terapeutica, S.A.U ( 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.

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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 | 7,991 |
| Customer relationships | 4,100 |
| Other assets | 188 |
| Accounts payable and accrued expenses | (3,165) |
| Deferred tax liability | (1,050) |
| | $ 20,344 |

Goodwill generated from this acquisition is not deductible for tax purposes. We estimate the useful lives of the customer relationships to be 5 years and have included them in other intangible assets, net in the accompanying consolidated balance sheets.

The operating results of IDT have been included in our professional diagnostic products reporting unit.

(iii) Acquisition of the 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 | $ 2,912 |
| Property, plant and equipment | 1,500 |
| Goodwill | 32,113 |
| Customer relationships | 12,000 |
| Trademark | 8,500 |
| Manufacturing know-how | 4,300 |

| | |
|---|---|
| Core technology | 500 |
| Accrued expenses | (3,723) |
| | $ 58,102 |

We have assigned indefinite lives to the trademark and product technology. 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

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

consolidated balance sheets. The weighted average amortization period for the acquired intangible assets with finite lives is 7.1 years.

The operating results of the Determine business have been included in our professional diagnostic products reporting unit.

(iv) Acquisition of Binax

On March 31, 2005, we acquired Binax, Inc. ( 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 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 | 5,304 |
| Inventories | 3,186 |
| Property, plant and equipment | 2,421 |
| Goodwill | 14,868 |
| Customer relationships | 11,700 |
| Core technology | 3,900 |
| Trademark | 4,500 |
| Non-compete agreement | 30 |
| Other assets | 1,146 |
| 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 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 years, 13 years and 7 years, respectively, 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 operating results of Binax have been included in our professional diagnostic products reporting unit.

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

(v) Acquisition of Ischemia

On March 16, 2005, we acquired Ischemia Technologies, Inc. ( Ischemia ), a privately held, venture-backed company that has 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.

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 |

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 operating results of Ischemia have been included in our professional diagnostic products reporting unit.

*(c) Recent Acquisitions*

In February 2007 we acquired substantially all of the assets of First Check Diagnostics LLC ( First Check ), a privately-held diagnostics company, for approximately $24.5 million in cash. In addition, we will pay an earn-out to First Check equal to the incremental revenue growth of the acquired products for 2007 and for the first nine months of 2008, as compared to the immediately preceding comparable periods.

First Check is the market leader in the rapidly-growing field of home testing for drugs of abuse, including marijuana, cocaine, methamphetamines and opiates. In addition, it offers tests, also sold through retail channels, for alcohol abuse, cholesterol monitoring and colon cancer screening.

*(d) Restructuring Plans Related to Business Combinations*

In connection with our acquisitions of BioStar, Ischemia, Ostex International, Inc. ( Ostex ), IVC Industries, Inc. (now operating as Inverness Medical Nutritionals Group or IMN ) and certain entities,

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

businesses and intellectual property of Unilever Plc (the Unipath business ), we recorded restructuring costs as part of the respective aggregate purchase prices in accordance with EITF No. 95-3.

During 2005, we established a restructuring plan in connection with our acquisition of BioStar and recorded restructuring costs of $0.5 million, 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 was nine, of which all were terminated as of December 31, 2006. Of the costs recorded during 2005, $10,000 remains unpaid as of December 31, 2006. Although we believe our plan and estimated exit costs are reasonable, actual spending for exit activities may differ from current estimated exit costs.

In connection with our acquisition of Ischemia in March 2005, we established a restructuring plan whereby we exited the current facilities of Ischemia in Denver, Colorado and combined its activities with our existing manufacturing and distribution facilities during the third quarter of 2005. Total severance costs associated with involuntarily terminated employees were estimated to be $1.6 million, of which all has been paid as of December 31, 2006. We estimated costs to vacate the Ischemia facilities to be approximately $135,000, of which $90,000 has been paid as of December 31, 2006. The total number of involuntarily terminated employees was 17, of which all were terminated as of December 31, 2006.

As a result of our acquisition of Ostex, 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 involuntarily terminated under the restructuring plan was 38, of which all were terminated as of December 31, 2006. Total severance costs associated with involuntarily terminated employees were $1.6 million, all of which has been paid as of December 31, 2006. Costs to vacate the Ostex facilities are $0.5 million, of which $0.2 million has been paid as of December 31, 2006. Additionally, the remaining costs to exit the operations, primarily facilities lease commitments, were $1.9 million, of which $1.5 million has been paid as of December 31, 2006. Total unpaid exit costs amounted to $0.7 million as of December 31, 2006.

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 includes severance costs for 47 involuntarily terminated employees and costs to vacate the warehouse, $1.5 million has been paid as of December 31, 2006.

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. Total exit costs, which primarily related to severance and early retirement obligations for 65 involuntarily terminated employees, were $4.1 million. As of December 31, 2006, $1.5 million, adjusted for foreign exchange effect, in exit costs remained unpaid.

*(e) Pro Forma Financial Information*

The following table presents selected unaudited financial information of our company, including Binax, Ischemia, the Determine business, BioStar, IDT and the Innovacon business including ABON as if the acquisitions of these entities had occurred on January 1, 2005. Pro forma results exclude adjustments for Advanced Clinical Systems Pty Ltd ( ACS ) and Clondiag as these acquisitions did not materially affect our results of operations. The pro forma results are derived from the historical financial results of the acquired

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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, 2005.

| (In thousands, except per share amounts) | 2006 | 2005 |
|---|---|---|
| | (unaudited) | |
| Pro forma net revenues | $ 582,901 | $ 528,212 |
| Pro forma net loss available to common stockholders basic and diluted | $ (14,449) | $ (2,972) |
| Pro forma net loss per common share basic and diluted(1) | $ (0.41) | $ (0.09) |

(1) Net loss per share amounts are computed as described in Note 13.

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

The following is a summary of goodwill and other intangible assets as of December 31, 2006:

| | Gross Carrying Amount | Accumulated Amortization | Net Carrying Value | Useful Life |
|---|---|---|---|---|
| | (in thousands, except useful life) | | | |
| **Amortized intangible assets:** | | | | |
| Core technology and patents | $ 111,550 | $ 23,818 | $ 87,732 | 1-20 years |
| Other intangible assets: | | | | |
| Supplier relationships | 14,320 | 6,093 | 8,227 | 10 years |
| Trademarks and trade names | 18,440 | 7,867 | 10,573 | 5-25 years |
| License agreements | 10,105 | 6,725 | 3,380 | 5-8.5 years |
| Customer relationships | 72,190 | 14,338 | 57,852 | 1.5-17.8 years |
| Manufacturing know-how | 7,800 | 4,076 | 3,724 | 10-15 years |
| Other | 540 | 502 | 38 | 2-7 years |
| Total other intangible assets | 123,395 | 39,601 | 83,794 | |
| Total intangible assets with finite lives | $ 234,945 | $ 63,419 | $ 171,526 | |
| **Intangible assets with indefinite lives:** | | | | |

| | | | |
|---|---|---|---|
| Goodwill | $ 439,369 | $ | $ 439,369 |
| Other intangible assets | 68,107 | | 68,107 |
| Total intangible assets with indefinite lives | $ 507,476 | $ | $ 507,476 |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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, except useful life) | | |
| **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 | 1.5-17.8 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 | |

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. In certain circumstances, such as certain customer relationship assets, accelerated amortization is recognized which reflect estimate of the cash flows. Amortization expense of intangible assets, which in the aggregate amounted to $21.8 million, $12.9 million and $10.4 million in 2006, 2005 and 2004, 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, 2006:

| | | (in thousands) |
|---|---|---|
| 2007 | $ | 23,907 |
| 2008 | $ | 21,843 |
| 2009 | $ | 19,942 |
| 2010 | $ | 19,339 |
| 2011 | $ | 18,153 |

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, 2006 did not indicate that goodwill related to our consumer diagnostic products and professional diagnostic products reporting units were

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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, 2004 | $ 86,078 | $ 135,077 | $ 221,155 |
| Acquisitions | | 103,815 | 103,815 |
| Other(1) | (904) | (1,856) | (2,760) |
| Goodwill, at December 31, 2005 | 85,174 | 237,036 | 322,210 |
| Acquisitions | 304 | 113,849 | 114,153 |
| Other(1) | 530 | 2,476 | 3,006 |
| Goodwill at December 31, 2006 | $ 86,008 | $ 353,361 | $ 439,369 |

(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, 2006, we had approximately $3.8 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, | |
|---|---|---|
| | 2006 | 2005 |
| | (in thousands) | |

| | | |
|---|---|---|
| Senior credit facilities | $ 44,775 | $ 89,000 |
| 8.75% Senior Subordinated notes | 150,000 | 150,000 |
| 10% Subordinated notes | | 20,000 |
| Line of credit | 6,785 | 2,212 |
| Other | 417 | 316 |
| | 201,977 | 261,528 |
| Less: Unamortized original issue discount | | (544) |
| Less: Current portion | (7,504) | (2,367) |
| | $ 194,473 | $ 258,617 |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

The following describes each of the above listed debt instruments:

*(a) Senior Credit Facilities*

As of December 31, 2005, $89.0 million of borrowings were outstanding under our senior credit facility. On February 8 and 9, 2006, we sold an aggregate 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.

On February 27, 2006, we borrowed $13.0 million under our European revolving line of credit to fund our acquisition of Clondiag. In March 2006, we entered into an amendment to our third amended and restated credit agreement. The amendment increased the total amount of credit available to us under the credit agreement to $155.0 million, from $100.0 million, consisting of a new $45.0 million U.S. term loan, a $40.0 million U.S. revolving line of credit, reduced from $60.0 million under the credit agreement prior to the amendment, and a $70.0 million European revolving line of credit, increased from $40.0 million under the credit agreement prior to the amendment. On March 31, 2006, in connection with our acquisition of the Innovacon business, we incurred $58.0 million in indebtedness under the credit agreement when we received the proceeds of the entire U.S. term loan and drew an additional $13.0 million under the U.S. revolving line of credit. On May 12, 2006, in the connection with the acquisition of the ABON facility, we drew $13.0 million under the U.S. revolving line of credit.

On August 23, 2006, we sold an aggregate 5.0 million shares of our common stock at $30.25 per share to funds affiliated with 17 accredited institutional investors in a private placement. Proceeds from the private placement were approximately $145.5 million, net of issuance costs of $5.7 million. Of this amount, we repaid principal outstanding on our revolving lines of credit under our senior credit facility of $54.0 million.

We began repaying the U.S. term loan in seven consecutive quarterly installments in October 2006, in an amount of $112,500, which is equal to 0.25% of the aggregate $45.0 million of U.S. term loan commitments. Our aggregate indebtedness under the amended credit agreement was $44.8 million as of December 31, 2006. On February 1, 2007, using a portion of the proceeds from our sale of 6.9 million shares of common stock in the first quarter of 2007 (Note 14), we paid the remaining principal balance outstanding and accrued interests under our senior credit facility. In accordance with SFAS No. 6, *Classification of Short-Term Obligations Expected to Be Refinanced*, we did not reclassify our February 2007 prepayment on our U.S. term loan and continued to carry the balance as long-term on our December 31, 2006 balance sheet.

Borrowings under the revolving lines of credit and term loan 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, for our revolving lines of credit depending on the quarterly adjustments that are based on our consolidated financial performance, and 4.00% or 2.75%, respectively, on our term loan. As of December 31, 2006, the interest rate under the U.S. term loan bore interest per annum of 9.35%. We recorded interest expense, including amortization of deferred financing costs, under these senior credit facilities in the aggregate amount of $8.9 million, $4.8 million and $2.0 million in 2006, 2005 and 2004, respectively.

As of December 31, 2006, accrued interest related to the senior credit facility amounted to $0.1 million.

Borrowings under the senior credit facility are secured by the stock of certain of our U.S. and foreign subsidiaries, substantially all of our intellectual property rights, substantially all of the assets of our businesses in the U.S. and a significant portion of the assets of our businesses outside the U.S. Under the senior credit agreement, as amended, we must comply with various financial and non-financial covenants. The primary

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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, 2006, 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. 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, 2006, 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 23 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

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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. All warrants issued in relation to this debt have been classified in equity, pursuant to the provisions of EITF No. 96-13.

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.

On September 8, 2006, in connection with the August 2006 equity offering, we repaid the 10% Subordinated Notes which were due to mature on September 20, 2008. The total payment aggregated $20.8 million, which represented the principal balance outstanding plus accrued and unpaid interest, as well as a prepayment penalty of $0.4 million. The prepayment penalty, along with the remaining unamortized deferred financing cost and unamortized original interest discount write-offs, aggregating $0.9 million, was charged to interest expense for the year ended December 31, 2006.

*(d) Maturities of Long-term Debt*

The following is a summary of the maturities of long-term debt outstanding on December 31, 2006:

| | (in thousands) |
|---|---|
| 2007 | $ 7,504 |
| 2008 | 44,469 |
| 2009 | 4 |
| 2010 | |
| 2011 | |
| Thereafter | 150,000 |
| | $ 201,977 |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(7) Capital Leases**

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, 2006:

| | (in thousands) |
|---|---|
| 2007 | $ 643 |
| 2008 | 399 |
| 2009 | 16 |
| 2010 | 4 |
| 2011 | 4 |
| Total future minimum lease payments | 1,066 |
| Less: Imputed interest | (67) |
| Present value of future minimum lease payments | 999 |
| Less: Current portion | (584) |
| | $ 415 |

At December 31, 2006, 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 | $ 263 |
| Buildings | 2,186 |
| | 2,449 |
| Less: Accumulated amortization | (1,750) |
| | $ 699 |

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 $0.8 million, $0.5 million and $0.4 million in 2006, 2005 and 2004, 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.

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

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, *Employers Accounting for Pensions*, and SFAS No. 88, *Employers 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.

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.

As discussed in Note 2, we adopted the recognition provisions of SFAS No. 158 as of December 31, 2006 and, accordingly recognized a liability for the unfunded status of our pension plans of $4.5 million. We

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

also recognized in accumulated other comprehensive income (loss) the prior service cost and net actuarial gain (loss) of this plan. Future changes to the funded status of these plans will be recognized in the year in which the change occurs through other comprehensive income.

Prior to December 31, 2006, we accounted for our defined benefit pension plan under SFAS No. 87. Accordingly, we recognized a pension liability of $1.8 million. There was no non-cash charge to accumulated other comprehensive income (loss) within stockholders equity at December 31, 2005.

We do not expect any non-cash pension expense in 2007.

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 2006 and 2005:

| | 2006 | 2005 |
|---|---|---|
| | (in thousands) | |
| **Change in projected benefit obligation** | | |
| Benefit obligation at beginning of year | $ 11,144 | $ 11,646 |
| Interest cost | 586 | 583 |
| Actuarial (gain) loss | (726) | 258 |
| Benefits paid | (129) | (122) |
| Foreign exchange impact | 1,495 | (1,221) |
| Benefit obligation at end of year | $ 12,370 | $ 11,144 |
| **Change in accumulated benefit obligation** | | |
| Benefit obligation at beginning of year | $ 8,141 | $ 8,304 |
| Interest cost | 586 | 583 |
| Actuarial (gain) loss | (726) | 258 |
| Benefits paid | (129) | (122) |
| Foreign exchange impact | 1,087 | (882) |
| Benefit obligation at end of year | $ 8,959 | $ 8,141 |
| **Change in plan assets** | | |
| Fair value of plan assets at beginning of year | $ 6,436 | $ 5,327 |
| Actual return on plan assets | 403 | 1,316 |
| Employer contribution | 553 | 546 |
| Benefits paid | (129) | (122) |
| Foreign exchange impact | 926 | (631) |

| | | |
|---|---|---|
| Fair value of plan assets at end of year | $ 8,189 | $ 6,436 |
| Funded status | $ (4,181) | $ (4,708) |
| Unrecognized net actuarial gain | | (1,414) |
| Unrecognized prior service cost | | 5,967 |
| Net amount recognized | $ (4,181) | $ (155) |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

The net amount recognized in the accompanying consolidated balance sheet that relates to the Defined Benefit Plan during 2006 and 2005 consists of:

| | 2006 | 2005 |
|---|---|---|
| | (in thousands) | |
| Accrued benefit liability | $ (733) | $ (1,672) |
| Intangible asset | 1,039 | 1,517 |
| Net amount recognized | $ 306 | $ (155) |

The measurement date used to determine plan assets and benefit obligations for the Defined Benefit Plan was December 31, 2006 and 2005.

The following table provides the weighted-average actuarial assumptions:

| | 2006 | 2005 |
|---|---|---|
| **Assumptions used to determine benefit obligations:** | | |
| Discount rate | 5.25% | 4.80% |
| Rate of compensation increase | 3.80% | 3.55% |
| **Assumptions used to determine net periodic benefit cost:** | | |
| Discount rate | 4.80% | 5.30% |
| Expected return on plan assets | 6.63% | 6.84% |
| Rate of compensation increase | 3.55% | 3.55% |

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:

| | 2006 | 2005 |
|---|---|---|
| | (in thousands) | |
| Interest cost | $ 586 | $ 583 |
| Expected return on plan assets | (461) | (360) |
| Amortization of net loss | (26) | 54 |

| | | |
|---|---|---|
| Net periodic benefit cost | $ 99 | $ 277 |

The plan assets of the Defined Benefit Plan comprise of a mix of stocks and fixed income securities and other investments. At December 31, 2006, 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 $0.6 million at December 31, 2006) to the Defined Benefit Plan in 2007. We expect benefits to be paid to plan participants of approximately $0.2 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 $1.2 million, $1.1 million and $0.3 million to the Defined Contribution Plan, which was recognized as an expense in the accompanying consolidated statement of operations, in 2006, 2005 and 2004, respectively.

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(9) Derivative Instruments**

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 during 2004, 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 matured during January and February 2006.

See Note 12(a) regarding our Chembio Diagnostics Inc. ( Chembio ) warrant which is accounted for as a derivative instrument.

**(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, 2006:

| | (in thousands) |
|---|---|
| 2007 | $ 10,454 |
| 2008 | 9,042 |
| 2009 | 7,104 |

| | |
|---|---|
| 2010 | 5,254 |
| 2011 | 5,187 |
| Thereafter | 30,762 |
| | $ 67,803 |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(10) Commitments and Contingencies (Continued)**

Rent expense relating to operating leases was approximately $11.8 million, $10.0 million and $7.4 million during 2006, 2005 and 2004, respectively.

*(b) Capital Expenditure Commitments*

At December 31, 2006, we had total outstanding non-cancelable equipment purchase commitments of $8.8 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 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.

In March, 2006, the U.S. Federal Trade Commission ( FTC ) opened a preliminary, non-public investigation into our then pending acquisition of the business we acquired from ACON Laboratories to determine whether this acquisition may be anticompetitive, and we subsequently received a Civil Investigative Demand and a subpoena requesting documents. We believe that we have fully responded to the Civil Investigative Demand and we are continuing to produce documents in connection with the subpoena and to otherwise cooperate with the FTC s investigation. We cannot predict whether the FTC will seek additional information or what the outcome of this investigation will be. The FTC generally has the power to commence administrative or federal court proceedings seeking injunctive relief or divestiture of assets. In the event that an order were to be issued requiring divestiture of significant assets or imposing other injunctive relief, our business, financial condition and results of operations could be materially adversely affected.

**(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 £30 million over three years to partially fund research and development programs focused on identifying novel biomarkers and near-patient and home-use tests for cardiovascular and other diseases ( the programs ). We agreed to invest £37.5 million in the programs over three years from the date of the agreement.

Through our subsidiary, Stirling Medical Innovations Limited ( Stirling ), we established a new research center in Stirling, Scotland, where we consolidated many of our existing cardiology programs and will 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, 2006, we had received approximately $40.9 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

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(11) Other Arrangements (Continued)**

expenses, subject to certain limitations. For the fiscal years ended December 31, 2006 and 2005, we recognized $18.4 million and $18.1 million of reimbursements, respectively, of which $16.6 million and $17.2 million, respectively, offset our research and development spending and $1.8 million and $0.9 million, respectively, reduced our general, administrative and marketing spending incurred by Stirling. Funds received from ITI in excess of amounts earned are considered deferred revenue and are included in accrued expenses and other current liabilities, the balance of which was $4.9 million as of December 31, 2006.

*(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.

**(12) Other Investments and Available-for-sale Securities**

(a) Investment in Chembio

In September 2006, we acquired 5% of Chembio, a developer and manufacturer of rapid diagnostic tests for infectious diseases, through the purchase of 40 shares of their preferred stock. The preferred stock pays a dividend of 7%, payable in cash or common stock. The aggregate purchase price of $2.0 million was paid in cash. In addition to the preferred stock, we received a warrant to purchase 625,000 shares of Chembio s common stock at $0.80 per share. Chembio s stock is publicly traded. The warrant, accounted for as a derivative instrument, had a fair value of approximately $0.4 million at the date of issuance. The fair value of this warrant was estimated at the time of issuance using the Black-Scholes pricing model and assuming no dividend yield, expected volatility of 116%, risk-free rate of 4.9% and a contractual term of 5 years. We mark to market the warrant over the contractual term. As of December 31, 2006, the warrant was valued at $0.4 million.

(b) Equity Method Investments

In November 2006, we acquired 40% of Vedalab S.A. ( Vedalab ), a French manufacturer and supplier of rapid diagnostic tests in the professional markets. The aggregate purchase price was $9.7 million which consisted of $7.6 million in cash, 49,787 shares of our common stock with an aggregate fair value of $2.0 million and $0.1 million in estimated direct acquisition costs. On the same date, we settled an ongoing patent infringement claim with Vedalab. Under the terms of the settlement, Vedalab paid to us $5.1 million and agreed to pay royalties on future sales ranging from 5% to 10%, depending on the products being sold in exchange for a license under certain patents to manufacture its current products as its facility in Alencon, France. The payment of $5.1 million has been included in as income our financial results for the year ended December 31, 2006, of which $4.6 million relates to periods prior to 2006 and has been included in other income, net and the remaining $0.5 million has been recorded as license and royalty revenue. We account for our 40% investment in Vedalab under the equity method of accounting in accordance with APB Opinion No. 18, *The Equity Method of Accounting for Investments in Common Stock.*

In May 2006, we acquired 49% of TechLab, Inc. ( TechLab ), a privately-held developer, manufacturer and distributor of rapid non-invasive intestinal diagnostics tests in the areas of intestinal inflammation, antibiotic associated diarrhea

and parasitology. The aggregate purchase price was $8.8 million which consisted of 303,417 shares of our common stock with an aggregate fair value of $8.6 million and $0.2 million in estimated direct acquisition costs. We account for our 49% investment in TechLab under the equity method of accounting, in accordance with APB Opinion No. 18. For the year ended December 31, 2006, we recorded

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

$0.6 million in other income, which represented our minority share of TechLab s profit in the respective periods.

*(c) Available-for-sale Securities*

Our investment in available-for-sale securities (long-term) consists of marketable equity securities purchased in December 2006. We currently intend to hold these investments indefinitely. On receipt, the shares were recorded at their market value. At December 31, 2006, their fair value was approximately $12.7 million, representing an unrealized holding gain of approximately $0.1 million which was recorded in other comprehensive income within stockholders equity in our consolidated balance sheet.

**(13) Loss per Share**

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

| | 2006 | 2005 | 2004 |
|---|---|---|---|
| | | (in thousands) | |
| **Numerator:** | | | |
| Net loss | $ (16,842) | $ (19,209) | $ (16,596) |
| Dividends, redemption interest and amortization of beneficial conversion feature related to Series A Preferred Stock (Note 14(b)) | | | (749) |
| Net loss available to common stockholders basic and diluted | $ (16,842) | $ (19,209) | $ (17,345) |
| **Denominator:** | | | |
| Denominator for basic and dilutive loss per share adjusted weighted average shares | 34,109 | 24,358 | 19,969 |
| Net loss per common share basic and diluted | $ (0.49) | $ (0.79) | $ (0.87) |

We had the following potential dilutive securities outstanding on December 31, 2006: options and warrants to purchase an aggregate of 4.1 million shares of our common stock at a weighted average exercise price of $20.75 per share. Potential dilutive securities were not included in the computation of diluted loss per share in 2006 because the inclusion thereof would be antidilutive.

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.

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(14) Stockholders Equity**

*(a) Common Stock*

As of December 31, 2006, we had 100.0 million shares of common stock, $0.001 par value, authorized, of which approximately 39.2 million shares were issued and outstanding, 8.1 million shares were reserved for issuance upon grant and exercise of stock options under current stock option plans and 0.3 million shares were reserved for issuance upon exercise of outstanding warrants.

In August 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.

In February 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 August 2006, we sold an aggregate 5.0 million shares of our common stock at $30.25 per share to funds affiliated with 17 accredited institutional investors in a private placement. Proceeds from the private placement were approximately $145.5 million, net of issuance costs of $5.7 million. Of this amount, we used $41.3 million for payments related to our acquisition of the ABON facility, $5.3 million to purchase the remaining 32.55% of Clondiag, $54.0 million to repay principal outstanding under our senior credit facility and $20.8 million to repay principal and interest outstanding, along with a prepayment penalty, under our 10% subordinated promissory notes, with the remainder of the net proceeds retained for general corporate purposes.

In January 2007, we sold an aggregate 6.0 million shares of our common stock at $39.65 per share through an underwritten public offering and in February 2007, our underwriters exercised in full an option to purchase an additional 0.9 million shares to cover over-allotments. Proceeds from the offering were approximately $261.3 million, net of issuance costs of $12.3 million, which include deductions for underwriting discounts and commissions and take into effect the reimbursement by the underwriters of a portion of our offering expenses. Of this amount, we used $44.9 million to repay principal outstanding and accrued interest on our term loan under our senior credit facility, with the remainder of the net proceeds retained for working capital and other general corporate purposes.

*(b) Preferred Stock*

As of December 31, 2006, 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. During 2004 and 2003, 0.2 million and 0.1 million shares of Series A Preferred Stock, respectively, were converted into 0.4 million and 0.2 million shares of our common stock, respectively. No shares of Series A Preferred Stock were outstanding as of December 31, 2006.

*(c) Stock Options and Awards*

In 2001, we adopted the 2001 Stock Option and Incentive Plan (as amended, the 2001 Plan ) which allows for the issuance of up to 8.1 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,

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(14) Stockholders Equity (Continued)**

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, 2006, there were 2.3 million shares available for future grant under the 2001 plan.

In August 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, vested ratably over 36 months; the remaining one-third, or 0.4 million shares, vested 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 was fully recourse to our chief executive officer. The note was due and payable on August 16, 2006 and bore interest at an annual rate of 4.99%. Interest income recorded under this note amounted to $0.3 million for the year ended December 31, 2006 and $0.5 million for each of the years ended December 31, 2005 and 2004. In August, 2006, the note and accrued interest were paid in full (Note 19).

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 notes were due and payable in December 2006 and bore interest at an annual rate of 3.97%, the applicable federal rate for a five-year note in effect during the month of exercise. The notes and accrued interest were paid in full in December 2006 (Note 19). Interest income recorded under these notes amounted to $0.2 million for each year ended December 31, 2006, 2005 and 2004, respectively. Shares issued upon exercise vested ratably over 36 months and were fully vested at December 31, 2004.

The following summarizes all stock option activity during the year ended December 31,:

| | 2006 | | 2005 | | 2004 | |
|---|---|---|---|---|---|---|
| | 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 | 3,902 | $ 18.82 | 3,619 | $ 16.58 | 3,398 | $ 15.85 |
| Granted | 666 | $ 31.88 | 809 | $ 26.67 | 394 | $ 21.75 |
| Exercised | (510) | $ 17.30 | (331) | $ 11.94 | (90) | $ 10.40 |
| Canceled/expired/forfeited | (283) | $ 21.81 | (195) | $ 21.48 | (83) | $ 18.12 |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Outstanding at December 31 | 3,775 | $ | 21.11 | 3,902 | $ | 18.82 | 3,619 | $ 16.58 |
| Exercisable at December 31 | 2,408 | $ | 17.16 | 2,424 | $ | 16.19 | 2,141 | $ 15.06 |

The aggregate intrinsic value of the options outstanding at December 31, 2006 was $66,664,961. The aggregate intrinsic value of the options exercisable at December 31, 2006 was $52,139,392.

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(14) Stockholders Equity (Continued)**

The following represents additional information related to stock options outstanding and exercisable at December 31, 2006:

| | Outstanding | | | Exercisable | |
|---|---|---|---|---|---|
| Exercise Price | Number of Shares (in thousands) | Weighted Average Remaining Contract Life (in years) | Weighted Average Exercise Price | Number of Shares (in thousands) | Weighted Average Exercise Price |
| $1.25-$14.92 | 378 | 3.57 | $ 8.11 | 376 | $ 8.08 |
| $15.35-$15.47 | 654 | 4.97 | $ 15.46 | 654 | $ 15.46 |
| $15.55-$16.76 | 465 | 5.58 | $ 16.27 | 391 | $ 16.29 |
| $16.95-$19.80 | 381 | 5.52 | $ 18.24 | 333 | $ 18.15 |
| $19.85-$22.75 | 400 | 5.53 | $ 21.28 | 353 | $ 21.31 |
| $22.78-$25.50 | 462 | 8.27 | $ 24.44 | 148 | $ 24.20 |
| $25.64-$28.03 | 458 | 8.52 | $ 27.51 | 109 | $ 27.82 |
| $28.10-$34.40 | 419 | 9.44 | $ 32.06 | 27 | $ 28.22 |
| $35.29-$139.72 | 153 | 9.27 | $ 38.82 | 12 | $ 52.82 |
| $165.96 | 5 | .91 | $ 165.96 | 5 | $ 165.96 |
| $1.25-$165.96 | 3,775 | 6.53 | $ 21.11 | 2,408 | $ 17.16 |

*(d) Warrants*

The following is a summary of all warrant activity during the three years ended December 31, 2006:

| | Number of Shares (in thousands) | Exercise Price | Weighted Average Exercise Price |
|---|---|---|---|
| Warrants outstanding and exercisable, December 31, 2003 | 712 | $ 3.81-$23.76 | $ 15.62 |
| Exercised | (9) | $ 11.55-$14.17 | $ 13.03 |

| | | | | | |
|---|---|---|---|---|---|
| Expired | (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 |
| Expired | (9) | $ | 14.15-$23.76 | $ | 18.66 |
| | | | | | |
| Warrants outstanding and exercisable, December 31, 2005 | 758 | $ | 3.81-$24.00 | $ | 16.47 |
| Exercised | (452) | $ | 3.88-$18.12 | $ | 16.51 |
| | | | | | |
| Warrants outstanding and exercisable, December 31, 2006 | 306 | $ | 3.81-$24.00 | $ | 16.42 |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(14) Stockholders Equity (Continued)**

The following represents additional information related to warrants outstanding and exercisable at December 31, 2006:

| | Outstanding and Exercisable | | |
|---|---|---|---|
| **Exercise Price** | **Number of Shares (in thousands)** | **Weighted Average Remaining Contract Life (in years)** | **Weighted Average Exercise Price** |
| $3.81-$3.93 | 4 | 3.48 | $ 3.87 |
| $4.48-$4.57 | 1 | 3.54 | $ 4.54 |
| $5.44-$5.57 | 4 | 3.58 | $ 5.53 |
| $7.37-$7.55 | 2 | 3.66 | $ 7.48 |
| $13.54-$18.12 | 220 | 4.97-5.72 | $ 14.40 |
| $24.00 | 75 | 8.25 | $ 24.00 |
| | 306 | 6.16 | $ 16.42 |

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 0.3 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, 2006. The value of warrants issued in connection with debt financings has yielded original issue discounts and additional interest expense of $0.5 million in 2006 and $0.2 million for both 2005 and 2004. All outstanding warrants have been classified in equity, pursuant to provision 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, 2006, 0.3 million shares had been issued under this plan.

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(15) Stock-based compensation**

In accordance with SFAS No. 123-R, our results of operations for the year ended December 31, 2006 reflected compensation expense for new stock options granted since January 1, 2006, and vested under our stock incentive plan and employee stock purchase plan and the unvested portion of previous stock option grants which vested during the year ended December 31, 2006. Stock-based compensation expense in the amount of $5.5 million ($4.9 million, net of tax) was reflected in our consolidated statements of operations for the year ended December 31, 2006, as follows:

| | (in thousands) |
|---|---|
| Cost of sales | $ 391 |
| Research and development | 1,390 |
| Sales and marketing | 682 |
| General and administrative | 2,992 |
| | $ 5,455 |

Prior to our adoption of SFAS No. 123-R, all tax benefits resulting from the exercise of stock options would have been reported as operating cash flows in our consolidated statements of cash flows. In accordance with SFAS No. 123-R, for the year ended December 31, 2006, the presentation of our cash flows reports the excess tax benefits from the exercise of stock options as financing cash flows. For the year ended December 31, 2006, excess tax benefits generated from option exercises amounted to $0.6 million.

The following assumptions were used to estimate the fair value of options granted during the year ended December 31, 2006, 2005 and 2004 using the Black-Scholes option-pricing model:

| | 2006 | 2005 | 2004 |
|---|---|---|---|
| Risk-free interest rate | 4.00-4.67% | 3.58-4.46% | 2.80-3.95% |
| Expected dividend yield | | | |
| Expected life | 6.25 years | 5 years | 5 years |
| Expected volatility | 41% | 45% | 47% |

The weighted average fair value under the Black-Scholes option pricing model of options granted to employees during 2006, 2005 and 2004 was $15.29, $11.85 and $9.86, respectively. All options granted during these periods were granted at fair market value on date of grants.

For the year ended December 31, 2006, in accordance with SFAS 123-R, we recorded compensation expense of $0.3 million related to our Employee Stock Purchase Plan. The fair value of the option component of the Employee Stock Purchase Plan shares were estimated at the date of grant using the Black-Scholes pricing model and assumed an expected volatility of 33%, a risk-free interest rate range of 4.55% to 4.99% and an expected life of 0.5 years. The

charge is included in general and administrative in the table above.

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(16) 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, 2006 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, 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 |
| Period change | 10,823 | (3,738) | 44 | 7,129 |
| Balance at December 31, 2006 | $ 17,875 | $ (3,738) | $ 44 | $ 14,181 |

(i) Other represents (realization of) unrealized gains on available-for-sale securities.

(ii) All of the components of accumulated other comprehensive income relate to our foreign subsidiaries except item (i), above. 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.

**(17) Income Taxes**

Our income tax provision in 2006, 2005 and 2004 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 Japan in Japan, and Inverness Medical Switzerland GmbH in Switzerland. Loss before provision for income taxes consists of the following:

| | 2006 | 2005 | 2004 |
|---|---|---|---|

| | (in thousands) | | |
|---|---|---|---|
| United States | $ (4,728) | $ (40,582) | $ (20,102) |
| Foreign | (6,387) | 28,192 | 5,781 |
| | $ (11,115) | $ (12,390) | $ (14,321) |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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:

| | 2006 | 2005 |
|---|---|---|
| | (in thousands) | |
| NOL and capital loss carryforwards | $ 86,516 | $ 71,926 |
| Tax credit carryforwards | 3,515 | 833 |
| Nondeductible reserves | 7,385 | 8,721 |
| Nondeductible accruals | 16,741 | 10,199 |
| Difference between book and tax bases of tangible assets | 1,624 | 932 |
| Difference between book and tax bases of intangible assets | 9,125 | 5,616 |
| Gross deferred tax asset | 124,906 | 98,227 |
| Less: Valuation allowance | (107,622) | (96,721) |
| Total deferred tax assets | 17,284 | 1,506 |
| Deferred tax liabilities: | | |
| Difference between book and tax bases of tangible assets | 7,068 | 2,171 |
| Difference between book and tax bases of intangible assets | 28,790 | 16,710 |
| Total deferred tax liability | 35,858 | 18,881 |
| Net deferred tax liability | $ 18,574 | $ 17,375 |
| Reported as: | | |
| Deferred tax assets, current portion | $ 5,332 | $ 844 |
| Deferred tax assets, long-term | 78 | 662 |
| Deferred tax liabilities, long-term | (23,984) | (18,881) |
| Net deferred tax liability | $ (18,574) | $ (17,375) |

As of December 31, 2006, we had approximately $188.7 million of domestic NOL carryforwards and $31.5 million of foreign NOL and foreign capital loss carryforwards, which either expire on various dates through 2026 or can be carried forward indefinitely. These loss carryforwards are available to reduce future federal and foreign taxable income, if any. These loss carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. The domestic NOL carryforwards include approximately $70.6 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, 2006, $17.3 million of our deferred tax asset pertains to acquired companies, the future benefits of which will be applied first to

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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.

Our China based manufacturing subsidiaries qualify for an income tax holiday. The tax holiday provides an income tax rate of 0% in 2006 and 2007. The income tax rate is scheduled to increase to 16% for 2008, 2009, and 2010, and then to the regular tax rate of 32% for 2011 and future years.

The estimated amount of undistributed earnings of our foreign subsidiaries is $38.7 million at December 31, 2006. 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.

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

| | 2006 | 2005 | 2004 |
|---|---|---|---|
| | | (in thousands) | |
| Current : | | | |
| State | $ 423 | $ 256 | $ 404 |
| Foreign | 5,315 | 575 | (365) |
| | 5,738 | 831 | 39 |
| Deferred : | | | |
| Federal | 3,152 | 2,650 | 2,341 |
| State | 289 | 247 | 209 |
| Foreign | (3,452) | 3,091 | (314) |
| | (11) | 5,988 | 2,236 |

| | | | |
|---|---|---|---|
| Total tax provision | $ 5,727 | $ 6,819 | $ 2,275 |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

| | 2006 | 2005 | 2004 |
|---|---|---|---|
| Statutory rate | 35% | 35% | 35% |
| Effect of losses and expenses not benefited | (28) | 1 | 1 |
| Rate differential on foreign earnings | (2) | 55 | 12 |
| Research and development benefit | 14 | (12) | 8 |
| State income taxes, net of federal benefit | (4) | (2) | (3) |
| Deferred tax on indefinite-lived assets | (31) | (24) | (21) |
| Accrual to return reconciliation | (9) | | |
| Change in valuation allowance | (27) | (108) | (48) |
| Effective tax rate | (52)% | (55)% | (16)% |

**(18) 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 $30.2 million, $16.8 million and $19.4 million in 2006, 2005 and 2004, respectively. With respect to cardiology expenditures in 2006 and 2005, the amount included in Corporate and Other is net of $16.6 million and $17.2 million, respectively, 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 $51.6 million at December 31, 2006 and $41.2 million at December 31, 2005.

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 2006, 2005, and 2004 are as follows:

| 2006 | Consumer Diagnostic Products | Vitamins and Nutritional Supplements | Professional Diagnostic Products | Corporate and Other | Total |
|---|---|---|---|---|---|

| | | | | | |
|---|---|---|---|---|---|
| | | | **(in thousands)** | | |
| Net revenue to external customers | $ 176,771 | $ 82,051 | $ 310,632 | $ | $ 569,454 |
| Operating income (loss) | $ 26,975 | $ (3,013) | $ 42,554 | $ (60,145) | $ 6,371 |
| Depreciation and amortization | $ 5,062 | $ 3,270 | $ 27,030 | $ 4,000 | $ 39,362 |
| Restructuring charge | $ 2,921 | $ | $ 7,625 | $ 2,587 | $ 13,133 |
| Stock-based compensation | $ | $ | $ | $ 5,455 | $ 5,455 |
| Assets | $ 314,815 | $ 49,896 | $ 625,560 | $ 95,500 | $ 1,085,771 |
| Expenditures for property, plant and equipment | $ 1,807 | $ 475 | $ 9,905 | $ 7,530 | $ 19,717 |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

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

| 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 | $ | $ 303 | $ | $ 5,100 |
| 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 |
|---|---|---|---|---|---|
| | | | (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 |

| | 2006 | 2005 | 2004 |
|---|---|---|---|
| | | (in thousands) | |
| **Revenue by Geographic Area:** | | | |
| United States | $ 335,405 | $ 244,719 | $ 222,640 |
| Europe | 136,971 | 111,838 | 100,693 |
| Other | 97,078 | 65,293 | 50,658 |
| | $ 569,454 | $ 421,850 | $ 373,991 |

| | December 31, | |
|---|---|---|
| | 2006 | 2005 |
| | (in thousands) | |
| **Long-lived Tangible Assets by Geographic Area:** | | |
| United States | $ 27,039 | $ 33,810 |
| United Kingdom | 31,470 | 31,316 |
| China | 15,815 | 1,593 |
| Other | 7,988 | 5,492 |
| | $ 82,312 | $ 72,211 |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(19) Related Party Transactions**

In June 2006, we issued 25,000 shares of our common stock as consideration for the acquisition of all of the capital stock of Innovative Medical Devices BVBA. The seller of the capital stock of Innovative Medical Devices BVBA is the spouse of the Vice President of our Consumer Diagnostics business unit.

In August 2006, our Chairman, Chief Executive Officer and President, paid us $11,197,096 in full satisfaction of his obligations to us, including principal and accrued interest, under a previously disclosed, five-year promissory note dated August 16, 2001. The promissory note was provided to us in connection with his purchase of 1,168,191 shares of our common stock in August, 2001 (Note 14).

In December 2006, one of our key executive officers, paid us $1,606,831 in full satisfaction of his obligations to us, including principal and accrued interest, under a previously disclosed, five-year promissory note dated August 16, 2001. The promissory note was provided to us in connection with his purchase of 250,000 shares of our common stock in August, 2001 (Note 14).

In December 2006, one of our key executive officers, paid us $2,571,320 in full satisfaction of his obligations to us, including principal and accrued interest, under a previously disclosed, five-year promissory note dated August 16, 2001. The promissory note was provided to us in connection with his purchase of 399,381 shares of our common stock in August, 2001 (Note 14).

**(20) 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, 2004 | $ 7,492 | $ 27,908 | $ (26,041) | $ 9,359 |
| Year ended December 31, 2005 | $ 9,359 | $ 25,015 | $ (24,626) | $ 9,748 |
| Year ended December 31, 2006 | $ 9,748 | $ 22,914 | $ (24,261) | $ 8,401 |

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, 2004 | $ 2,089 | $ 6,761 | $ (4,724) | $ 4,126 |
| Year ended December 31, 2005 | $ 4,126 | $ 10,057 | $ (6,441) | $ 7,742 |
| Year ended December 31, 2006 | $ 7,742 | $ 6,661 | $ (6,184) | $ 8,219 |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(21) Restructuring Activities**

The following table sets forth the aggregate restructuring charges for 2006, 2005, and 2004:

| | 2006 | 2005 | 2004 |
|---|---|---|---|
| | | (in thousands) | |
| Severance | $ 2,886 | $ 2,229 | $ 1,725 |
| Fixed asset and inventory write-off | 6,989 | 2,259 | |
| Intangible asset write-off | 2,722 | | |
| Facility and other exit costs | 536 | 612 | |
| | $ 13,133 | $ 5,100 | $ 1,725 |

*(a) Recent Restructuring Plans*

On May 22, 2006, we committed to a plan to cease operations at our manufacturing facility in San Diego, California and to write off certain excess manufacturing equipment at other impacted facilities. Additionally, on June 7, 2006, we committed to a plan to reorganize the sales and marketing and customer service functions in certain of our U.S. professional diagnostic companies. As a result of these restructuring plans, we recorded $12.1 million in restructuring charges during the year ended December 31, 2006. The $12.1 million charge included $2.5 million related to severance charges, $6.9 million related to impairment charges on fixed assets and inventory and $2.7 million related to an impairment charge on an intangible asset. This restructuring charge consisted of $8.8 million charged to cost of sales, $2.9 million charged to research and development, $0.2 million charged to sales and marketing expenses and $0.2 million charged to general and administrative expenses, of which $1.9 million, $7.6 million and $2.6 million were included in our consumer diagnostic products, professional diagnostic products and corporate and other business segments, respectively.

We expect to complete these plans during the first half of 2007. Including the charges recorded through December 31, 2006, we expect the total restructuring charge related to these plans to be approximately $12.6 million, with additional charges of $0.1 million relating to severance and $0.4 million relating to facility exit and closure costs. The total number of employees to be involuntarily terminated under these plans is 132, of which 86 have been terminated as of December 31, 2006. Of the $2.5 million related to severance charges, $1.6 million remains unpaid as of December 31, 2006.

*(b) 2005 Restructuring Plan*

On May 9, 2005, we committed to a plan to cease operations at our facility in Galway, Ireland. During the year ended December 31, 2006, we recorded a net restructuring gain of $3.2 million, of which $0.4 million related to charges for severance, early retirement and outplacement services, $0.1 million related to an impairment charge of fixed assets, $0.6 million related to facility closing costs and $4.3 million related to foreign exchange gains as a result of recording

a cumulative translation adjustment to other income relating primarily to this plan of termination. The charges for the year ended December 31, 2006 consisted of $0.7 million charged to cost of goods sold, $0.4 million charged to general and administrative and $4.3 million in gains recorded to other expense. Of the net restructuring gain of $3.2 million included in our net loss for the year ended December 31, 2006, the $1.1 million loss and the $4.3 million gain were included in our consumer diagnostic products and corporate and other business segments, respectively. Additionally, during the year ended December 31, 2006, we recorded a $1.4 million gain on the sale of our CDIL facility in Ireland which has been recorded in loss on dispositions, net in our consolidated statements of operations and is included in our corporate and other business segment for these periods (Note 22).

Net restructuring charges since the commitment date consist of $2.6 million related to severance, early retirement and outplacement services, $2.4 million related to impairment of fixed assets and inventory and

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(21) Restructuring Activities (Continued)**

$1.2 million related to facility closing costs, offset by $4.3 million related to net foreign exchange gains relating primarily to this plan of termination and a $1.4 million gain on the sale of the manufacturing facility. Of the total $6.2 million restructuring charges recorded in operating income, $5.9 million and $0.3 million were included in our consumer diagnostic products and professional diagnostic products business segments, respectively. The $4.3 million and $1.4 million gains are included in our corporate and other business segment. The plan of termination is substantially complete as of December 31, 2006 and all 113 employees under this plan have been involuntarily terminated. All costs related to severance, early retirement, outplacement services and facility closing costs have been paid as of December 31, 2006.

*(c) 2004 Restructuring Plan*

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

*(d) Restructuring Reserves*

The following table summarizes our liabilities related to restructuring activities:

| | Balance at Beginning of Period | Additions to the reserve | Amounts Paid | Other (i) | Balance at End of Period |
|---|---|---|---|---|---|
| | | | (in thousands) | | |
| Year ended December 31, 2004 | $ | $ 1,725 | $ (1,725) | $ | $ |
| Year ended December 31, 2005 | $ | $ 2,841 | $ (1,892) | $ | $ 949 |
| Year ended December 31, 2006 | $ 949 | $ 3,422 | $ (2,820) | $ 14 | $ 1,565 |

(i) Represents foreign currency translation adjustment.

**(22) Loss on Dispositions, net**

During 2006, we recorded a net loss on dispositions of $3.5 million. Included in this net loss is a $4.9 million charge associated with management s decision to dispose of our Scandinavian Micro Biodevices ApS ( SMB ) research operation, which is part of our professional diagnostic products and corporate and other business segments, of which

$2.0 million is related to impaired assets, primarily goodwill associated with SMB, and a $2.9 million estimated loss on the sale of SMB. The sale of this operation was completed in the fourth quarter of 2006. The net loss on dispositions also includes an offsetting $1.4 million gain on the sale of an idle manufacturing facility in Galway, Ireland, as a result of our 2005 restructuring plan. This facility was associated with our consumer diagnostic products business segment.

**(23) 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, 2006. The guarantee is full and unconditional. Separate financial statements of the Guarantor Subsidiaries are not presented because we

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(23) Guarantor Financial Information (Continued)**

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, 2006 and the balance sheets as of December 31, 2006 and 2005 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.

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(23) Guarantor Financial Information (Continued)**

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**
**CONSOLIDATING STATEMENT OF OPERATIONS**
**For the Year Ended December 31, 2006**
**(in thousands)**

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| Net product sales | $ 23,100 | $ 334,471 | $ 272,028 | $ (77,469) | $ 552,130 |
| License and royalty revenue | | 306 | 17,018 | | 17,324 |
| **Net revenue** | 23,100 | 334,777 | 289,046 | (77,469) | 569,454 |
| Cost of sales | 22,395 | 232,429 | 165,515 | (80,108) | 340,231 |
| **Gross profit** | 705 | 102,348 | 123,531 | 2,639 | 229,223 |
| Operating expenses: | | | | | |
| Research and development | 1,750 | 7,705 | 44,211 | | 53,666 |
| Sales and marketing | 4,096 | 48,684 | 41,665 | | 94,445 |
| General and administrative | 21,345 | 18,999 | 30,899 | | 71,243 |
| Loss on dispositions, net | | | 3,498 | | 3,498 |
| **Operating (loss) income** | (26,486) | 26,960 | 3,258 | 2,639 | 6,371 |
| Equity in earnings of subsidiaries, net of tax | 14,716 | | | (14,716) | |
| Interest expense, including amortization of original issue discounts and write-off of deferred financing cost | (16,895) | (6,206) | (20,461) | 16,992 | (26,570) |
| Other income (expense), net | 13,213 | 4,686 | 8,298 | (17,113) | 9,084 |
| **(Loss) income before provision for income taxes** | (15,452) | 25,440 | (8,905) | (12,198) | (11,115) |
| Provision for income taxes | 1,390 | 2,012 | 1,935 | 390 | 5,727 |
| **Net (loss) income** | $ (16,842) | $ 23,428 | $ (10,840) | $ (12,588) | $ (16,842) |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(23) Guarantor Financial Information (Continued)**

**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 and royalty 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 (loss) 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 | 12,579 | 16,927 | 30,484 | | 59,990 |
| **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 original issue discounts and write-off of deferred financing cost | (16,502) | (2,941) | (7,839) | 5,487 | (21,795) |
| Other income (expense), net | 1,461 | 6,762 | 17,442 | (5,487) | 20,178 |
| **(Loss) income before provision for 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) |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(23) Guarantor Financial Information (Continued)**

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

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| Net product sales | $ 20,842 | $ 214,132 | $ 180,685 | $ (50,227) | $ 365,432 |
| License and royalty 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 |
| **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 original issue discounts and write-off of deferred financing cost | (15,345) | (5,699) | (5,893) | 4,823 | (22,114) |
| Other income (expense), net | 4,870 | 1,857 | 1,503 | (4,823) | 3,407 |
| **(Loss) income before provision (benefit) for 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) |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(23) Guarantor Financial Information (Continued)**

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**
**CONSOLIDATING BALANCE SHEET**
**December 31, 2006**
**(in thousands)**

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| **ASSETS** | | | | | |
| **Current Assets:** | | | | | |
| Cash and cash equivalents | $ 16,350 | $ 19,755 | $ 34,999 | $ | $ 71,104 |
| Accounts receivable, net of allowances | 2,538 | 53,544 | 44,306 | | 100,388 |
| Inventories, net | 5,984 | 38,804 | 37,116 | (3,582) | 78,322 |
| Deferred tax assets | | | 5,332 | | 5,332 |
| Prepaid expenses and other current assets | 2,238 | 2,444 | 15,716 | | 20,398 |
| Intercompany receivables | 57,748 | 67,589 | 8,542 | (133,879) | |
| **Total current assets** | 84,858 | 182,136 | 146,011 | (137,461) | 275,544 |
| Property, plant and equipment, net | 2,098 | 24,710 | 55,504 | | 82,312 |
| Goodwill | 71,136 | 109,116 | 259,117 | | 439,369 |
| Other intangible assets with indefinite lives | | 21,120 | 46,987 | | 68,107 |
| Core technology and patents, net | 18,496 | 13,304 | 55,932 | | 87,732 |
| Other intangible assets, net | 14,321 | 31,098 | 38,375 | | 83,794 |
| Deferred financing costs, net, and other non-current assets | 6,314 | 2,277 | 4,627 | | 13,218 |
| Other investments and available-for-sale securities | 387,818 | (778) | 10,835 | (362,258) | 35,617 |
| Deferred tax assets | | | 78 | | 78 |
| Intercompany notes receivable | 355,074 | 56,267 | | (411,341) | |
| **Total assets** | $ 940,115 | $ 439,250 | $ 617,466 | $ (911,060) | $ 1,085,771 |
| **LIABILITIES AND STOCKHOLDERS EQUITY** | | | | | |
| **Current liabilities:** | | | | | |
| Current portion of long-term debt | $ | $ 450 | $ 7,054 | $ | $ 7,504 |
| Current portion of capital lease obligations | | 551 | 33 | | 584 |

| | | | | | |
|---|---|---|---|---|---|
| Accounts payable | 5,302 | 19,998 | 21,042 | | 46,342 |
| Accrued expenses and other current liabilities | 24,920 | 19,721 | 42,642 | 518 | 87,801 |
| Intercompany payables | 40,803 | 35,967 | 60,179 | (136,949) | |
| **Total current liabilities** | 71,025 | 76,687 | 130,950 | (136,431) | 142,231 |
| **Long-term liabilities:** | | | | | |
| Long-term debt, net of current portion | 150,000 | 44,325 | 148 | | 194,473 |
| Capital lease obligations, net of current portion | | 360 | 55 | | 415 |
| Deferred tax liabilities | 4,903 | 8,149 | 10,932 | | 23,984 |
| Other long-term liabilities | 49 | 305 | 10,176 | | 10,530 |
| Intercompany notes payable | | 85,983 | 322,275 | (408,258) | |
| **Total long-term liabilities** | 154,952 | 139,122 | 343,586 | (408,258) | 229,402 |
| **Stockholders equity** | 714,138 | 223,441 | 142,930 | (366,371) | 714,138 |
| **Total liabilities and stockholders equity** | $ 940,115 | $ 439,250 | $ 617,466 | $ (911,060) | $ 1,085,771 |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(23) Guarantor Financial Information (Continued)**

**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, net | 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 | 2,051 | 4,266 | | 13,013 |
| Other investments | 297,607 | (866) | 160 | (296,445) | 456 |
| Deferred tax assets | | | 662 | | 662 |
| 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 |
| **Total liabilities and stockholders equity** | $ 619,218 | $ 344,231 | $ 396,568 | $ (568,851) | $ 791,166 |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(23) Guarantor Financial Information (Continued)**

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**
**CONSOLIDATING STATEMENT OF CASH FLOWS**
**For the Year Ended December 31, 2006**
**(in thousands)**

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| **Cash Flows from Operating Activities:** | | | | | |
| Net (loss) income | $ (16,842) | $ 23,428 | $ (10,840) | $ (12,588) | $ (16,842) |
| Adjustments to reconcile net (loss) income to net cash (used in) provided by operating activities: | | | | | |
| Equity in earnings of subsidiaries, net of tax | (14,716) | | | 14,716 | |
| Interest expense related to amortization and write-off of non-cash original issue discount, non-cash beneficial conversion feature and deferred financing costs | 1,937 | 1,213 | 1,008 | | 4,158 |
| Non-cash loss related to currency hedge and interest swap agreement | (217) | | | | (217) |
| Non-cash stock-based compensation expense | 5,455 | | | | 5,455 |
| Charge for in-process research and development | | | 4,960 | | 4,960 |
| Non-cash value of settlement of litigation | | | | | |
| Impairment of long-lived assets | | 5,646 | 3,927 | | 9,573 |
| (Gain) loss on sale of fixed assets | | 9 | (1,537) | | (1,528) |
| Interest in minority investments | (635) | | | | (635) |
| Depreciation and amortization | 4,989 | 13,378 | 20,995 | | 39,362 |
| Deferred income taxes | 84 | 2,186 | (2,551) | (128) | (409) |
| Other non-cash items | 159 | | 555 | | 714 |
| Changes in assets and liabilities, net of acquisitions: | | | | | |
| Accounts receivable, net | (194) | (8,931) | (4,721) | | (13,846) |
| Inventories, net | 1,534 | 5,533 | (4,382) | (2,518) | 167 |
| Prepaid expenses and other current assets | (10) | 740 | (816) | | (86) |

| | | | | | |
|---|---|---|---|---|---|
| Intercompany payable (receivable) | (12,998) | (15,288) | 28,409 | (123) | |
| Accounts payable | 3,757 | (5,652) | 2,105 | | 210 |
| Accrued expenses and other current liabilities | 2,510 | (4,962) | 5,228 | 518 | 3,294 |
| Other non-current liabilities | | 28 | (88) | | (60) |
| **Net cash (used in) provided by operating activities** | (25,187) | 17,328 | 42,252 | (123) | 34,270 |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(23) Guarantor Financial Information (Continued)**

**INVERNESS MEDICAL INNOVATIONS, INC. AND SUBSIDIARIES**
**CONSOLIDATING STATEMENT OF CASH FLOWS (Continued)**
**For the Year Ended December 31, 2006**
**(in thousands)**

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| **Cash Flows from Investing Activities:** | | | | | |
| Purchases of property, plant and equipment | (558) | (3,332) | (15,827) | | (19,717) |
| Proceeds from sale of property, plant and equipment | | 15 | 2,229 | | 2,244 |
| Cash paid for purchase of Ischemia, net of cash acquired | (99) | | | | (99) |
| Cash paid for purchase of IDT Spain, net of cash acquired | (237) | | | | (237) |
| Cash paid for purchase of Clondiag, net of cash acquired | (5,338) | | (12,238) | | (17,576) |
| Cash paid for purchase of Innovacon business including ABON, net of cash acquired | (64,128) | | (48,515) | | (112,643) |
| Cash paid for purchase of other businesses and intellectual property | (801) | (109) | | | (910) |
| Cash paid for investments in minority interests and available-for-sale securities | (14,455) | | (11,362) | | (25,817) |
| Increase in other assets | (933) | (133) | (3,011) | | (4,077) |
| **Net cash used in investing activities** | (86,549) | (3,559) | (88,724) | | (178,832) |
| **Cash Flows from Financing Activities:** | | | | | |
| Cash paid for financing costs | (79) | (1,358) | (1,350) | | (2,787) |
| Proceeds from issuance of common stock, net of issuance costs | 234,961 | | | | 234,961 |
| Stock-based compensation tax benefit | 567 | | | | 567 |
| | | (15,225) | (32,654) | | (47,879) |

| | | | | | |
|---|---|---|---|---|---|
| Net (payments) proceeds under revolving line of credit | | | | | |
| Repayments of notes payable | (20,000) | | | | (20,000) |
| Repayments of notes receivable | 14,691 | | | | 14,691 |
| Principal payments of capital lease obligations | | (511) | (35) | | (546) |
| Intercompany notes payable (receivable) | (103,247) | 15,000 | 88,247 | | |
| **Net cash provided by (used in) financing activities** | 126,893 | (2,094) | 54,208 | | 179,007 |
| Foreign exchange effect on cash and cash equivalents | (3) | | 2,269 | 123 | 2,389 |
| **Net increase in cash and cash equivalents** | 15,154 | 11,675 | 10,005 | | 36,834 |
| **Cash and cash equivalents, beginning of year** | 1,196 | 8,080 | 24,994 | | 34,270 |
| **Cash and cash equivalents, end of year** | $ 16,350 | $ 19,755 | $ 34,999 | $ | $ 71,104 |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(23) Guarantor Financial Information (Continued)**

**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 original issue discount, non-cash beneficial conversion feature and write-off of deferred financing costs | 1,181 | 665 | 499 | | 2,345 |
| Non-cash loss related to currency hedge and interest swap 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, net | (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 |
| | (915) | (2,092) | 7,503 | | 4,496 |

| | | | | | |
|---|---|---|---|---|---|
| Accrued expenses and other current liabilities | | | | | |
| Other non-current liabilities | | (3) | 342 | | 339 |
| **Net cash (used in) provided by operating activities** | (29,279) | 12,831 | 42,343 | 698 | 26,593 |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(23) Guarantor Financial Information (Continued)**

**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 for purchase of Ischemia, net of cash acquired | (4,211) | 115 | | | (4,096) |
| Cash paid for purchase of Binax, net of cash acquired | (9,528) | 1,556 | | | (7,972) |
| Cash paid for purchase of the Determine business | (1,602) | | (56,500) | | (58,102) |
| Cash paid for purchase of BioStar | (53,607) | | | | (53,607) |
| Cash paid for purchase of IDT Spain, net of cash acquired | | | (20,030) | | (20,030) |
| Cash paid for purchase of other businesses and intellectual property | (63) | (141) | (4,971) | | (5,175) |
| Increase 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 (payments) 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 |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(23) Guarantor Financial Information (Continued)**

**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 currency hedge and 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 non-cash items | | 40 | (76) | | (36) |
| Changes in assets and liabilities, net of acquisitions: | | | | | |
| Accounts receivable, net | 1,255 | (1,049) | (4,301) | | (4,095) |
| Inventories, net | (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 |
| | (7,319) | (3,141) | 19,344 | (589) | 8,295 |

| | |
|---|---|
| **Net cash (used in) provided by operating activities** | |

Table of Contents

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

**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Continued)**

**(23) Guarantor Financial Information (Continued)**

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

| | Issuer | Guarantor Subsidiaries | Non-Guarantor Subsidiaries | Eliminations | Consolidated |
|---|---|---|---|---|---|
| **Cash Flows from Investing Activities:** | | | | | |
| Purchases of property, plant and equipment | (1,635) | (7,836) | (10,918) | | (20,389) |
| Proceeds from sale of property, plant and equipment | | 244 | 141 | | 385 |
| Cash paid for purchase of other businesses and intellectual property | (4,791) | (1,624) | (5,994) | | (12,409) |
| (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 |