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## **2007 Annual Report**

July 3, 2008

## To Our Stockholders

Thank you for the opportunity to serve as acting Chief Executive Officer of IVAX Diagnostics, Inc. It was an exciting and challenging year for me and I wish to share with you a summary of the financial highlights and important events of 2007, a transitional year in our development, as well as the progress we made in the first quarter of 2008.

For the full year 2007, revenues increased 2.3% to \$19,976,000 from \$19,523,000 for the full year 2006. For the full year 2007, our net loss was \$10,434,000 compared to net loss of \$2,809,000 for the full year 2006. As previously announced, our net loss for 2007 increased significantly primarily as a result of our third quarter 2007 non-cash write-off of goodwill totaling \$5,852,000 and the substantial changes we undertook during 2007 in an effort to improve our cash flow and increase our stockholders' value in the future. These changes primarily included our third quarter 2007 decision to focus on the development of the Mago<sup>®</sup> 4, the upgraded version of our Mago<sup>®</sup> Plus instrument, as a platform for marketing our kits and to place any further development of the PARSEC<sup>®</sup> System on hold indefinitely. Although these changes largely contributed to our increased net loss during 2007, as they resulted in our third quarter 2007 non-cash write-off of PARSEC<sup>®</sup> System related assets totaling \$1,674,000 and our fourth quarter 2007 recording of severance related costs of \$1,998,000, we believe that these changes have better positioned us to focus on our core business and to attempt to achieve profitability in 2008 and beyond.

We believe that our financial results for the first quarter of 2008 represent the first step in validating the strategic changes we undertook during 2007 and achieving our goal of improved financial performance on a sustained and continuous basis. For the first quarter of 2008, we recorded net income of \$345,000, or earnings of \$0.01 per share, compared to net loss of \$238,000, or loss of \$0.01 per share, for the first quarter of 2007. Additionally, our net revenues for the first quarter of 2008 were \$5,242,000, an increase of \$296,000, or 6%, compared to our net revenues for the first quarter of 2007. Our efforts to contain expenses directly contributed to a reduction in operating expenses in the first quarter of 2008 compared to the first quarter of 2007. Further, at the same time we reduced our marketing expenses and general and administrative expenses during the first quarter of 2008, we also achieved consolidated revenue growth.

We expect our improved financial foundation to provide us with opportunities to develop additional strategic business and scientific relationships. We also expect that our focus on the development of our proprietary Mago<sup>®</sup> 4 platform will allow us to broaden our product portfolio of diagnostic assays and continue to deliver to our customers the technological innovation that they expect from us.

We are enthusiastic about the future of IVAX Diagnostics and are dedicated in our efforts to serve our stockholders, customers and employees well.



Kevin D. Clark  
Acting Chief Executive Officer and  
Chief Operating Officer

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

**FORM 10-K**

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

For the fiscal year ended December 31, 2007

Commission File Number 1-14798

**IVAX Diagnostics, Inc.**

(Exact name of registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**11-3500746**  
(I.R.S. Employer  
Identification No.)

**2140 North Miami Avenue, Miami, Florida 33127**

(Address of principal executive offices, including zip code)

**(305) 324-2300**

(Registrant's telephone number, including area code)

**Securities Registered Pursuant to Section 12(b) of the Act:**

**Common Stock, par value \$0.01**  
(Title of class)

**American Stock Exchange**  
(Name of each exchange on which registered)

**Securities Registered Pursuant to Section 12(g) of the Act: None**

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2007, was approximately \$7,465,000 computed by reference to the price at which the common equity was last sold on the American Stock Exchange on such date.

As of March 26, 2008, there were 27,649,887 shares of common stock outstanding.

**Documents Incorporated by Reference:**

None.

**IVAX Diagnostics, Inc.**  
**Annual Report on Form 10-K**  
**for the year ended December 31, 2007**

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## PART I

### ITEM 1. BUSINESS

**General.** We are the parent corporation of the following three subsidiaries:

- Delta Biologicals, S.r.l.;
- Diamedix Corporation; and
- ImmunoVision, Inc.

Through these subsidiaries, we develop, manufacture, and market diagnostic test kits, or assays, and automated systems that are used to aid in the detection of disease markers primarily in the areas of autoimmune and infectious diseases. These tests, which are designed to aid in the identification of the causes of illness and disease, assist physicians in selecting appropriate patient treatment. Most of our tests are based on Enzyme Linked ImmunoSorbent Assay, or ELISA, technology, a clinical testing methodology used worldwide. Specific tests are prepared using a 96 well microplate format whereby specific antigens are typically coated on the wells of a microplate during the manufacturing process. A test using ELISA technology involves a series of reagent additions to the microplate causing a reaction that results in a visible color in the wells. The amount of color is directly proportionate to the amount of the specific analyte in the patient sample. Our kits are designed to be performed either manually or in an automated format. In addition to our line of diagnostic kits, we also design and manufacture laboratory instruments that perform the tests and provide fast and accurate results, while reducing labor costs. Our existing proprietary instruments, named the Mago<sup>®</sup> Plus and Aptus<sup>®</sup> systems, include a fully-automated ELISA processor operating with our own user-friendly software, allowing customers to perform tests in an automated mode. We have updated the Mago<sup>®</sup> Plus instrument to include the capability to process ELISA and ImmunoFluorescent Antibody, or IFA, assays simultaneously. Currently, we are only marketing this updated version of the Mago<sup>®</sup> Plus outside of the United States. We are also developing an upgraded version of the Mago<sup>®</sup> Plus instrument, named the Mago<sup>®</sup> 4, which is expected to be able to perform both ELISA and IFA techniques simultaneously, perform positive sample identification and utilize disposable pipette tips. We believe that the Mago<sup>®</sup> 4 will offer an enhanced automation solution to customers who prefer a more compact, lower-priced instrument with features and benefits similar to many of the other instruments currently offered in the marketplace. It is anticipated that, during 2008, we will only market the Mago<sup>®</sup> 4 outside of the United States. We intend to seek, but have not yet received, all necessary regulatory approvals for the Mago<sup>®</sup> 4, and, accordingly, commercial deliveries of the Mago<sup>®</sup> 4 will await our receipt of such regulatory approvals. We intend to continually evaluate the advisability of marketing the Mago<sup>®</sup> 4 in the United States in the future based on, among other factors, current market conditions, our success in marketing the Mago<sup>®</sup> 4 abroad and our results of operations and business prospects. We also develop, manufacture and market raw materials, such as antigens used in the production of diagnostic kits.

We previously anticipated that the PARSEC<sup>®</sup> System, a proprietary instrument system which we were developing and which we believed would enable customers to utilize not only ELISA-based kits, but also other methods such as IFA and chemiluminescent-based assays in the future, would become our primary product. However, as previously disclosed, as a result of continuing delays in the development of the PARSEC<sup>®</sup> System, we engaged a third party consulting firm to independently evaluate the PARSEC<sup>®</sup> System and the status of its development. The consulting firm reported that it was not likely that we would be able to meet our previously announced target for submitting our 510(k) application for the PARSEC<sup>®</sup> System to the United States Food and Drug Administration, or FDA, primarily as a result of the status of the proprietary operating system and other software components utilized in the development and operation of the PARSEC<sup>®</sup> System. After reviewing the consulting firm's findings and conducting our own internal reviews, we determined that the Mago<sup>®</sup> 4 can be developed and brought to market more quickly, using fewer resources and in a more cost-effective manner than completing the development of the PARSEC<sup>®</sup> System and its proprietary operating system and other software components. Accordingly, during the fourth quarter of 2007, we decided to change our strategic direction to focus on the development of the Mago<sup>®</sup> 4 as a platform for marketing our kits and to place any further development of the PARSEC<sup>®</sup> System on hold indefinitely.

Our management reviews financial information, allocates resources and manages the business as two segments defined by geographic region. One segment—the domestic region—contains our subsidiaries located in the United States and corporate operations. Our other segment—the Italian region—contains our subsidiary located in Italy. For additional information about our two segments, see Note 12 to our Consolidated Financial Statements.

Delta, which IVAX Corporation, or IVAX, acquired in 1991, was established in 1980. From its facility located in Pomezia, Italy, it manufactures scientific and laboratory instruments, including its proprietary Mago® Plus and Aptus® systems, which include hardware, reagents, and software, and it is currently developing the Mago® 4. The Mago® Plus and Aptus® systems, in association with over 200 specific ELISA-based assays acquired from Diamedix and third parties, as well as a complete line of allergy products, are sold directly in Italy through Delta's independent sales force and sales representatives, most of whom work exclusively for Delta. Delta also sells in Italy other diagnostic products manufactured by third parties. Approximately 80% of Delta's revenue generated from customers in Italy is revenue from government owned hospitals and the remaining 20% is revenue from private laboratories. Thus, sales in Italy are heavily concentrated in the public sector, which impacts the timing of collections. Delta also serves as the distribution and support center for selling these same products to distributors located in other European and international markets outside Italy.

Diamedix was established in 1986 after it acquired all of the assets and retained substantially all of the personnel of Cordis Laboratories, Inc., a company that had developed, manufactured and marketed diagnostic equipment since 1962. IVAX acquired Diamedix in 1987. Diamedix' products are sold in the United States through Diamedix' sales force. Diamedix markets 50 assays that the FDA has cleared and that are available to be run in conjunction with the Mago® Plus and Aptus® systems. Most of these assays are sold under the trade name immunosimplicity®. Diamedix is located in Miami, Florida.

Since 1985, ImmunoVision has been developing, manufacturing and marketing autoimmune reagents and research products for use by research laboratories and commercial diagnostic manufacturers. These manufacturers (including Diamedix) use these antigens to produce autoimmune diagnostic kits. IVAX acquired ImmunoVision in 1995. ImmunoVision is located in Springdale, Arkansas.

**Merger.** On November 21, 2000, IVAX and the pre-merger IVAX Diagnostics, Inc., which then was a wholly-owned subsidiary of IVAX and which was incorporated in 1996 by IVAX to be the parent corporation of Diamedix, Delta and ImmunoVision, entered into a definitive merger agreement with us, pursuant to which the pre-merger IVAX Diagnostics would merge with and into us, with us as the surviving corporation. The merger was consummated on March 14, 2001, and our name was changed from "b2bstores.com Inc." to "IVAX Diagnostics, Inc." As a result of the merger, approximately 70% of the issued and outstanding shares of our common stock became owned by IVAX and our business became that of the pre-merger IVAX Diagnostics.

We were incorporated on June 28, 1999 under the laws of the State of Delaware. Prior to the merger, we operated an Internet web site that was specifically designed to assist business customers in the operation and development of their businesses. The web site was designed to provide business customers with access to products and supplies, a network of business services and business content. On December 1, 2000, we ceased all web site related operations and permanently shut down our web site.

**Parent Company.** On July 25, 2005, IVAX, which then owned approximately 72.3% of the outstanding shares of our common stock, entered into a definitive agreement and plan of merger with Teva Pharmaceutical Industries Limited, or Teva, providing for IVAX to be merged into a wholly-owned subsidiary of Teva. On January 26, 2006, the merger was consummated and IVAX became a wholly-owned subsidiary of Teva for an aggregate purchase price of approximately \$3.8 billion in cash and 123 million Teva ADRs. The transaction was reported to be valued, for accounting purposes, at \$7.9 billion, based on the value of the Teva ADRs during the five trading day period commencing two trading days before the date of the definitive agreement and plan of merger. As a result of the merger, Teva now, indirectly through its wholly-owned IVAX subsidiary, owns approximately 72.3% of the outstanding shares of our common stock.

**Market.** Our products are primarily associated with the in vitro diagnostics market. In vitro diagnostic assays are tests that are used to detect specific substances, usually either antigens or antibodies, outside the body. This usually involves using a blood sample or other bodily fluid sample for testing. The market for in vitro diagnostic products consists of reference laboratory and hospital laboratory testing, testing in physician offices, and over the counter testing, in which testing can be performed at home by the consumer. Industry analysts have estimated that the world market for in vitro diagnostics was \$32.2 billion in 2006 and estimated to grow at a rate of 7% annually. Of this total \$32.2 billion market, the world immunoassay market in which we operate is estimated by industry analysts to be \$5.5 billion. We have focused our efforts on the niche market for autoimmune and infectious disease immunoassay products. Our ELISA autoimmune product line consists of 20 test kits that the FDA has cleared. These include test kits for screening antinuclear antibodies and specific tests to measure antibodies to dsDNA, SSA, SSB, Sm, Sm/RNP, Scl 70, Jo-1, Rheumatoid Factor, MPO, PR-3, TPO, TG, and others. These products are used for the diagnosis and monitoring of autoimmune diseases, including Systemic Lupus Erythematosus, or SLE, Rheumatoid Arthritis, Mixed Connective Tissue Disease, Sjogren's Syndrome, Scleroderma, and Dermatopolymyositis. Our infectious disease product line, together with kits obtained from third party companies, includes 30 kits that the FDA has cleared, including Toxoplasma IgG, Toxoplasma IgM, Rubella IgG, Rubella IgM, Cytomegalovirus, or CMV, IgG, CMV IgM, Herpes Simplex Virus, or HSV, IgG, HSV IgM, Measles, Varicella Zoster Virus, or VZV, Lyme Disease, H. pylori, Mumps, six different Epstein-Barr Virus, or EBV, kits and others. In international markets, this line of autoimmune and infectious disease products is supplemented by additional products that are obtained from third party companies.

We believe that the market trend for in vitro diagnostic products is towards increased laboratory automation that would allow laboratories to lower their overall costs. We believe that our proprietary Mago® 4, Mago® Plus and Aptus® systems should enable laboratories to achieve more automation in the test sectors in which we compete.

We are seeking to differentiate ourselves from our competitors through our proprietary instrument systems. We believe that the cost advantage we currently enjoy from our own manufacture of the Mago® Plus and Aptus® systems, as well as the cost advantage we believe we will enjoy based on our plan to internally manufacture the Mago® 4, in each case coupled with our production of certain autoimmune reagents at ImmunoVision and our production of diagnostic test kits at Diamedix, should position us to target new product markets for growth beyond the niche market for autoimmune and infectious disease immunoassay products in which we currently compete.

**Research and Development.** We devote substantial resources for research and development. For the years ended December 31, 2007 and 2006, we incurred \$2.2 million and \$1.9 million, respectively, for research and development activities.

As a result of our change in strategic direction to focus on the development of the Mago® 4 as a platform for marketing our kits and to place any further development of the PARSEC® System on hold indefinitely, our research and development efforts, which were previously targeted primarily towards the development of the PARSEC® System, are currently targeted primarily towards the development of the Mago® 4. While there is no assurance that we will be successful, we are seeking to expand the test kits menu we offer in the autoimmune and infectious disease testing sectors and considering moving into additional diagnostic test sectors such as HIV and hepatitis. In September 2004, we signed a license agreement with an Italian diagnostics company that allows us access to its technology for manufacturing certain hepatitis products. This agreement is expected to enable us to become competitive in markets outside of the United States by providing us with the technology that, over time, would allow us to internally manufacture many of our own hepatitis products with the "CE Marking," as well as internally manufacture our own raw materials for these hepatitis products. As a result of our change in strategic direction described above, the timeframe during which we had expected to begin marketing hepatitis test kits manufactured at our Italian facilities has been delayed.

**Sales and Marketing.** We currently market our products in the United States through our own sales force to hospitals, reference laboratories, clinical laboratories and research laboratories, as well as to other commercial companies that manufacture diagnostic products. We also sell some of our products to pharmaceutical and biotechnology companies. We market our products in certain international markets through a network of independent distributors. We market and sell our products in Italy through a network of salespersons and sales agents, most of whom work on an exclusive basis for Delta. We also sell our products in other global markets through a number of independent distributors. Sales personnel are trained to demonstrate our products in the laboratory setting. Our marketing and technical service departments located in Miami, Florida, Springdale, Arkansas and Pomezia, Italy support their efforts. We participate in a number of industry trade shows in the United States and Europe.

The products we market are purchased principally by healthcare providers that typically bill third party payors such as governmental programs (e.g., Medicare and Medicaid), private insurance plans and managed care plans, for healthcare services provided to their patients. Governmental reimbursement policies are subject to rapid and significant changes in the United States at both the federal and state levels and in other countries. Private third party payors are increasingly negotiating the prices charged for medical products and services. A third party payor may deny reimbursement if it determines that a device was not used in accordance with cost-effective treatment methods, was experimental, or for other reasons.

In Italy, as well as in most other countries in Western Europe, our products are sold predominantly to public hospital laboratories, which are managed by government structures, either directly or indirectly. In most cases, in Italy, our products are sold through tenders for multiple year periods. Due to the efforts exercised by many governments to contain healthcare costs, there has been a constant effort to consolidate laboratory units and, consequently, the bid process continues to become even more competitive.

Our business is not considered seasonal in nature, but our Italian operations may be slightly affected by the general reduction in business activity in Europe during the traditional summer vacation months.

Our business is not materially affected by order backlog or working capital issues.

**Competition.** We compete on a worldwide basis and there are numerous competitors in the specific market sectors in which we offer our products. These competitors range from major pharmaceutical companies to development stage diagnostic companies. Many of these companies, such as Siemens Medical Solutions, are much larger and have significantly greater financial, technical, manufacturing, sales and marketing resources than us.

The diagnostics industry has experienced considerable consolidation through mergers and acquisitions in the past several years. At the same time, the competition in test sectors, such as autoimmune, is very fragmented as it is comprised of primarily small companies with no single company possessing a dominant market position. We compete in the marketplace on the basis of the quality of our products, price, instrument design and efficiency, as well as our relationships with customers. In addition to Siemens Medical Solutions, our competitors include Bio-Rad Laboratories, DiaSorin, Meridian Bioscience, Inc., Inverness Medical Innovations, Inc. and Trinity Biotech plc.

The in vitro diagnostic market in which we sell many of our products is highly competitive. The market for our products is characterized by continual and rapid technological developments that have resulted in, and will likely continue to result in, substantial improvements in product function and performance. Our success will depend, in part, on our ability to anticipate changes in technology and industry requirements and to respond to technological developments on a timely basis either internally or through strategic alliances. Several companies have developed, or are developing, scientific instruments and assays that compete or will compete directly with products we market. Many existing and potential competitors have substantially greater financial, marketing, research and technological resources, as well as established reputations for success in developing, manufacturing,

selling and servicing products, than us. Competitors that are more vertically integrated than us may have more flexibility to compete effectively on price. We expect that existing and new competitors will continue to introduce products or services that are, directly or indirectly, competitive with those that we sell. Such competitors may succeed in developing products that are more functional or less costly than those sold by us and may be more successful in marketing such products.

**Personnel.** As of December 31, 2007, we had approximately 98 full time employees, of whom 12 were managerial, 41 were technical and manufacturing, 13 were administrative and 32 were sales and marketing.

**Intellectual Property.** The technology associated with the design and manufacture of the Mago<sup>®</sup> 4, Mago<sup>®</sup> Plus and Aplus<sup>®</sup> instruments is not protected by patent registrations or license restrictions. The Mago<sup>®</sup> Plus instrument has been our primary product. In the future, we expect that the Mago<sup>®</sup> 4 will become our primary platform for marketing our kits.

On March 14, 2001, we entered into a use of name license with IVAX whereby IVAX granted us a non-exclusive, royalty free license to use the name "IVAX." IVAX may terminate this license at any time upon 90 days' written notice. Upon termination of this license, we are required to take all steps reasonably necessary to change our name as soon as is practicable. The termination of this license by IVAX could have a material adverse effect on our ability to market our products and on us.

**Governmental Regulation.** The testing, manufacturing, and sale of our products are subject to regulation by numerous governmental authorities, principally the FDA. To comply with FDA requirements, we must, among other things, manufacture our products in conformance with the FDA's medical device Quality System Regulation, or good manufacturing practices. Diamedix is listed as a registered establishment with the FDA and Delta has received ISO 9001 certification. The FDA classifies medical devices into three classes (Class I, II or III). Class I devices are subject to general controls, such as good manufacturing practices, and are generally not subject to pre-market notification, or 510(k)s. When required, pre-market notifications must be submitted to the FDA before products can be commercially distributed. Class II devices are subject to the same general controls, may be subject to special controls and/or performance standards and are usually subject to pre-market notification. Class III devices typically require Pre-Market Approvals by the FDA to ensure their safety and effectiveness. All of our products are classified as Class I or II devices.

For new devices that require FDA clearance prior to being introduced to the market, a 510(k) relating to the device is submitted to the FDA which provides data to show that the device is substantially equivalent to other devices that were introduced into the marketplace prior to May 1976, or pre-amendment devices. Once the 510(k) is submitted to the FDA, the FDA has 90 days to review the submission. During the review period, the FDA may ask for additional information. If the FDA requests additional information, then the review period is stopped until the FDA has received all of the requested additional information, at which point the review period is then restarted. Upon 510(k) clearance by the FDA, the FDA issues a letter assigning a 510(k) number and stating that the FDA has "determined that your device is substantially equivalent to legally marketed predicate devices . . . and you may therefore market the device subject to general controls provisions of the [Food, Drug and Cosmetics] Act." The FDA's 510(k) clearance does not provide an approval of the device itself, but instead is a determination by the FDA that the device is much the same as other devices (predicates) already approved by the FDA. FDA issued 510(k) clearance letters are made available in a database administered by the FDA as evidence that the product is approved for sale in the United States. Almost all of the products we sell have received 510(k) clearance.

Customers using diagnostic tests for clinical purposes in the United States are additionally regulated under the Clinical Laboratory Improvement Amendments of 1988, or CLIA. CLIA is intended to ensure the quality and reliability of all medical testing in laboratories in the United States by requiring that any healthcare facility in which testing is performed meets specified standards in the areas of personnel qualification, administration, participation in proficiency testing, patient test management, quality control, quality assurance and inspections.

The products we sell are also subject to extensive forms of regulation by other governmental authorities in the United States and other countries, including, among other things, the regulation of the approval, manufacturing and testing controls, labeling, marketing and sale of diagnostic devices. As a general matter, foreign regulatory requirements for medical devices are becoming increasingly stringent. In the European Union, a single regulatory approval process has been created and approval is represented by the "CE Marking." "CE" is an abbreviation for *Conformite Europeene*, or European Conformity, and the "CE Marking" when placed on a product indicates compliance with the requirements of the applicable regulatory directive. Medical devices properly bearing the "CE Marking" may be commercially distributed throughout the European Union. "CE Marking" must be obtained for all medical devices commercially distributed throughout the European Union although the medical devices may have already received FDA clearance. In order to be commercially distributed throughout the European Union, certain of our products must bear the "CE Marking." All of the products that we currently sell throughout the European Union are in conformity with the applicable "CE" regulations under the *In Vitro Diagnostics Directive*. We have also received an ISO 13485:2003 certificate, thereby giving us approval for Europe and Canada.

Failure to comply with any governmental regulation can result in fines, unanticipated compliance expenditures, interruptions of production, product recalls or suspensions and criminal prosecution. The process of obtaining regulatory approval is rigorous, time consuming and costly. In addition, product approvals can be withdrawn if we fail to comply with regulatory standards or if unforeseen problems occur following initial marketing. Domestic and foreign regulations are subject to change and extensive changes in regulation may increase our operating expenses.

We are also subject to numerous federal, state and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control and disposal of hazardous or potentially hazardous substances.

Our employment relations in Italy are governed by numerous regulatory and contractual requirements, including national collective labor agreements and individual employer labor agreements. These arrangements address a number of specific issues affecting our working conditions including hiring, work time, wages and benefits and termination of employment. We must make significant payments in order to comply with these requirements.

**Available Information.** We file various reports with the Securities and Exchange Commission. We make available, free of charge, through our Internet web site, these reports, including our annual report 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 soon as reasonably practicable after such documents are electronically filed with or furnished to the Securities and Exchange Commission. Our Internet web site is [www.ivaxdiagnostics.com](http://www.ivaxdiagnostics.com). Information contained in our Internet web site is not part of this Annual Report on Form 10-K and shall not be incorporated by reference herein.

## ITEM 1A. RISK FACTORS

You should carefully consider the risks described below. These and other risks could materially and adversely affect our business, operating results or financial condition. The risks described below are not the only risks we face. Additional risks not presently known to us or other factors that we do not presently perceive to present significant risks to us at this time may also impair our operations. You should also refer to the other information contained or incorporated by reference in this Annual Report on Form 10-K.

### **The future success of our business depends on our development, manufacture and marketing of new products.**

Our future success is largely dependent upon our ability to develop, manufacture and market commercially successful new scientific instruments and assays. Delays in the development, manufacture or marketing of new products will impact our operating results, financial condition and cash flows. Each of the steps in the development, manufacture and marketing of our products, as well as the process taken as a whole, involves significant periods of time and expense. There can be no assurance that:

- any of our products presently under development, if and when fully developed and tested, will perform as expected,
- we will obtain necessary regulatory approvals in a timely manner, if at all, or
- we can successfully and profitably produce and market any of our products.

Any of the above factors may materially and adversely affect our business, prospects, operating results, financial condition or cash flows.

### **Our strategic initiatives, including our automation strategy, our development and commercial release of the upgraded version of our existing Mago<sup>®</sup> Plus instrument and the expansion of our menu of test kits, may not be successful.**

Our test kits are designed to be performed either manually or in an automated format. We also design and manufacture our laboratory instruments to perform tests in a fully-automated mode. In furtherance of our automation strategy, we are developing an upgraded version of our existing Mago<sup>®</sup> Plus instrument, which is named the Mago<sup>®</sup> 4. It is anticipated that, during 2008, we will only market the Mago<sup>®</sup> 4 outside of the United States. We intend to seek, but have not yet received, all necessary regulatory approvals for the Mago<sup>®</sup> 4, and, accordingly, commercial deliveries of the Mago<sup>®</sup> 4 will await our receipt of such regulatory approvals. There can be no assurance that we will be able to obtain all necessary regulatory approvals for the Mago<sup>®</sup> 4 when anticipated, or at all. We intend to continually evaluate the advisability of marketing the Mago<sup>®</sup> 4 in the United States in the future based on, among other factors, current market conditions, our success in marketing the Mago<sup>®</sup> 4 abroad and our results of operations and business prospects. Additionally, there can be no assurance that our financial condition, operating results or cash flows or the judgments and estimates we have made with respect to our inventory, property and equipment, equipment on lease, goodwill and product intangibles will not be impacted by the anticipated timing of the commercial release of the Mago<sup>®</sup> 4.

We expect that the Mago<sup>®</sup> 4 will become our primary platform for marketing our kits. However, the development and marketing of new or enhanced products, including, without limitation, the Mago<sup>®</sup> 4, is a complex and uncertain process. Accordingly, we cannot be certain that:

- the Mago<sup>®</sup> 4 will be available when expected, or at all,
- the Mago<sup>®</sup> 4 will perform as expected,
- the Mago<sup>®</sup> 4 will become our primary platform for marketing our kits,
- the Mago<sup>®</sup> 4 will enable us to expand the menu of test kits we offer,

- the Mago® 4 will be a source of revenue growth for us,
- we will receive financial benefits or achieve improved operating results after the commercial release of the Mago® 4,
- we will be successful in the marketing of the Mago® 4, or
- customers will integrate the Mago® 4 into their operations as readily as expected.

Additionally, in an effort to expand the menu of test kits we offer, in September 2004, we entered into a license agreement with an Italian diagnostics company that allows us access to its technology for manufacturing certain hepatitis products. We expect this agreement to enable us to become competitive in markets outside of the United States by providing us with technology that, over time, would allow us to internally manufacture many of our own hepatitis products with the "CE Marking," as well as internally manufacture our own raw materials for those hepatitis products. However, there remains a risk that we will not be able to obtain product technology that would enable us to manufacture hepatitis products or, if we obtain such product technology, that we will not be able to manufacture hepatitis products or obtain regulatory approval for these products. As a result of our change in strategic direction to focus on the development of the Mago® 4 as a platform for marketing our kits and to place any further development of the PARSEC® System on hold indefinitely, the timeframe during which we had expected to begin marketing hepatitis test kits manufactured at our Italian facilities has been delayed.

Any of the above factors may materially and adversely affect our business, prospects, operating results, financial condition or cash flows.

**Our implementation of our new strategic direction, which includes focusing on the development of the Mago® 4 as a platform for marketing our kits and placing any further development of the PARSEC® System on hold indefinitely, could adversely affect our business, prospects, operating results, financial condition or cash flows.**

We have decided that we intend to change our strategic direction by focusing on the development of the Mago® 4 as a platform for marketing our kits and placing any further development of the PARSEC® System on hold indefinitely. There can be no assurance that we will successfully implement this change in strategic direction. Accordingly, there can be no assurance that the PARSEC® System will ever be available. Furthermore, our international activities associated with the PARSEC® System will be adversely impacted. Additionally, the timeframe during which we had expected to begin marketing hepatitis test kits to be manufactured at our Italian facilities pursuant to a technology license has been delayed. At December 31, 2007, we had approximately \$1.2 million of intangible assets and approximately \$0.1 million of accrued payables relating to the technology license. While we believe we will be able to bring hepatitis test kits to market, if the progress of our efforts to begin marketing hepatitis test kits is further adversely impacted, then we could be required to record an impairment charge with respect to all or a portion of these intangible assets and pay all or a portion of these accrued payables. Any of these factors could materially and adversely affect our business, prospects, operating results, financial condition or cash flows.

**Our future success depends on the development of new markets.**

Our success depends, in large part, on the introduction and acceptance by hospitals, clinics and laboratories of our new diagnostic products and our ability to broaden sales of our existing products to current and new customers. In order to penetrate the market more effectively, we will need to expand our sales and marketing activities by, among other things:

- increasing our sales force,
- expanding our promotional activities,
- developing additional third party strategic distributorships, and
- participating in trade shows.

There is no assurance that these or other activities or programs will be successful. The failure of such activities or programs could have a material adverse effect on our business, prospects, operating results or financial condition.

**Making or changing judgments and estimates regarding our inventory may adversely affect our financial condition and operating results.**

There are inherent uncertainties involved in the estimates and judgments we make regarding our inventory and changes in these estimates and judgments could have a material adverse effect on our financial condition, operating results and cash flows. As of December 31, 2007, our total inventories included approximately \$0.1 million in Mago® 4 instrumentation and instrument components. There can be no assurance that we will not have to make or change judgments and estimates regarding our inventory as a result of any delay of the commercial launch of, future design changes to, the development of improved instrument versions of or future demand for, the Mago® 4, nor can there be assurance that such judgments and estimates, or changes in judgments and estimates, will not adversely impact our financial condition and operating results.

**We may not be able to use inventories of parts and products purchased or made before receiving final regulatory clearance or beginning full commercial marketing.**

From time to time, we purchase or make significant quantities of parts and products prior to the date on which we receive final regulatory clearance or begin our full commercial marketing. As of December 31, 2007, our total inventories included approximately \$0.1 million in Mago® 4 instrumentation and instrument components. The production of pre-launch inventories for our products, including, without limitation, the Mago® 4, involves the risks, among others, that the parts and products may not be approved for commercial marketing by the applicable regulatory authorities on a timely basis, or at all, that the launch of the products may be significantly postponed or, as a result of the discontinuation of such products or otherwise, cancelled, or that we may not be able to find alternative uses for such inventory. If any of these events were to occur, then we may be required to reassess the net realizable value of the related inventory and could, in such case, incur a charge to write down the value of such inventory, which would adversely affect our operating results in the period in which the determination or charge is or was made.

**Our own manufacture of scientific instruments, reagents and test kits may not provide us with anticipated cost savings or competitive advantages.**

We have sought to differentiate ourselves from our competitors through our proprietary instrument systems. While some of our competitors offer proprietary instruments, other competitors use third parties to manufacture these instruments for them. We manufacture our Mago® Plus and Aptus® instruments, and are currently developing and plan to manufacture the Mago® 4, at Delta, our wholly-owned subsidiary in Italy. Additionally, our wholly-owned subsidiary, ImmunoVision, produces certain autoimmune reagents and our wholly-owned subsidiary, Diamedix, produces diagnostic test kits. There can be no assurance that we will realize cost savings or competitive advantages from our own production of scientific instruments, reagents or test kits.

**We may not be able to increase the volume of our reagent production to meet increased demand.**

Our "reagent rental" program in which customers make reagent kit purchase commitments with us that typically last for a period of three to five years and our sales of these reagent kits are principal sources of revenue for us. If the demand for reagent kits increases, there can be no assurance that we will be able to increase the volume of our reagent kit production in order to meet such demand. Any failure to meet the demand for reagent kits could have a material adverse effect on our business, prospects, operating results or financial condition.

**Our research and development expenditures may not result in commercially successful products.**

We devote substantial resources to research and development to update and improve our existing products, as well as to develop new products and technologies. During 2007, we incurred approximately \$2.2 million on our research and development efforts. We may in the future increase the amounts we spend on research and development depending upon, among other things:

- the outcome of clinical testing of products under development,
- delays or changes in government required testing or approval procedures,
- technological and competitive developments,
- strategic marketing decisions, and
- liquidity.

As a result, our research and development expenditures may adversely impact our earnings and cash flows in the short term. Additionally, there is no assurance that:

- our research and development expenditures will result in the development of new products or product enhancements,
- we will successfully complete products currently under development,
- we will obtain regulatory approval for any such products, or
- any approved product will be produced in commercial quantities, at reasonable costs, and be successfully marketed.

**The markets for our products are highly competitive and subject to rapid technological change.**

The markets for our products are highly competitive and are characterized by continual and rapid technological developments that have resulted, and will likely continue to result, in substantial improvements in product function and performance. Our success will depend, in part, on our ability to anticipate changes in technology and industry requirements and to respond to technological developments on a timely basis either internally or through strategic alliances. Several companies have developed, or are developing, scientific instruments and assays that compete, or will compete, directly with products marketed by us. Many existing and potential competitors have substantially greater financial, marketing, research and technological resources, as well as established reputations for success in developing, manufacturing, selling and servicing products, than us. Competitors that are more vertically integrated than us may have more flexibility to compete effectively on price. We expect that existing and new competitors will continue to introduce products or services that are, directly or indirectly, competitive with those sold by us. Such competitors may succeed in developing products that are more functional or less costly than those sold by us and may be more successful in marketing such products. These and other changes and innovations in the rapidly changing medical technology market may negatively affect the sales of the products we market. There can be no assurance that we will be able to compete successfully in this market or that technology developments by our competitors will not render our current or future products or technologies obsolete. If we fail to effectively compete or adapt to changing technology, it could have a material adverse effect on our business, prospects, operating results or financial condition.

**Our success depends on key personnel, the loss of whom could disrupt our business.**

Our business is dependent on the active participation of our principal executive officers. The loss of the services of any of these individuals could adversely affect our business and future prospects. In addition, our success is dependent on our ability to retain and attract additional qualified management, scientists, engineers, developers and regulatory and other personnel. Competition for such talent is intense and there can be no assurance that we will be able to attract and retain such personnel.

**Our business is dependent on third party distributors.**

Although our direct sales force consummates the majority of our sales, we also engage third party distributors to sell our products. In Italy, our products are sold directly through Delta's independent sales force and sales representatives, most of whom work exclusively for Delta. There is no assurance that third party distributors or independent sales personnel will achieve acceptable levels of sales or that, if any of our existing arrangements expire or terminate, we will be able to replace any distributors or sales personnel on terms advantageous to us, or at all. Further, there is no assurance that we will be able to expand our distribution network by adding additional distributors or sales personnel. If third party distributors or independent sales personnel cease to promote our products, or if we are unable to make acceptable arrangements with distributors or sales personnel in other markets, our business, prospects, operating results or financial condition could be materially adversely affected.

**We depend on our proprietary rights and cannot be certain of their confidentiality and protection.**

Our success depends, in large part, on our ability to protect our current and future technologies and products and to defend our intellectual property rights. The technology associated with the design and manufacture of the Mago® Plus, Mago® 4 and Aptus® instruments is not protected by patent registrations or license restrictions. There can be no assurance that our competitors will not gain access to our trade secrets and proprietary and confidential technologies or that they will not independently develop similar or competing trade secrets and technologies. If others develop competing instruments or other products, then this could erode our competitive advantage and materially harm our business.

We also rely on trade secrets, unpatented proprietary know-how and continuing technological innovation. We use confidentiality agreements with licensees, suppliers, employees and consultants to protect our trade secrets, unpatented proprietary know-how and continuing technological innovation. There can be no assurance that these parties will not breach their agreements with us. We also cannot be certain that we will have adequate remedies for any breach. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. Furthermore, we cannot be sure that our trade secrets and proprietary technology will not otherwise become known or that our competitors will not independently develop similar or competing trade secrets and proprietary technology. We also cannot be sure, if we do not receive patents for products arising from research, that we will be able to maintain the confidentiality of information relating to our products.

**Third parties may claim that we infringe their proprietary rights, which may prevent us from manufacturing and selling some of our products or result in claims for substantial damages.**

Technology-based companies are often very litigious and are often subject to unforeseen litigation. Therefore, although our business philosophy is to respect intellectual property rights, we face the risk of adverse claims and litigation alleging infringement of intellectual property rights belonging to others. These claims could result in costly litigation and could divert management's and technical personnel's attention from other matters. The outcome of any claim is difficult to predict because of the uncertainties inherent in litigation. In addition, regardless of the merits of any infringement claims, these claims could cause us to lose our right to develop our discoveries or commercialize our products in certain markets or could require us to pay monetary damages or royalties to license proprietary rights from third parties. Furthermore, we cannot be certain that we would be able to obtain these licenses on terms we believe to be acceptable. As a result, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could have a material and adverse effect on our business, prospects, operating results or financial condition.

**There are inherent uncertainties involved in estimates, judgments and assumptions used in the preparation of financial statements in accordance with GAAP. Any changes in estimates, judgments and assumptions used could have a material adverse effect on our business, financial position and operating results.**

The consolidated financial statements included in the periodic reports we file with the Securities and Exchange Commission are prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of financial statements in accordance with GAAP involves making estimates, judgments and assumptions that affect reported amounts of assets (including goodwill and other intangible assets), liabilities and related reserves, revenues, expenses and income. This includes estimates, judgments and assumptions for assessing the recoverability of our goodwill and other intangible assets, pursuant to Statement of Financial Accounting Standards, or SFAS, No. 142, *Goodwill and Other Intangible Assets*, and SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. If any estimates, judgments or assumptions change in the future, we may be required to record additional expenses or impairment charges. Any resulting expense or impairment loss would be recorded as a charge against our earnings and could have a material adverse impact on our financial condition and operating results. Estimates, judgments and assumptions are inherently subject to change in the future, and any such changes could result in corresponding changes to the amounts of assets (including goodwill and other intangible assets), liabilities, revenues, expenses and income. Any such changes could have a material adverse effect on our financial position and operating results.

On an on-going basis, we evaluate our estimates, including, among others, those relating to:

- product returns,
- allowances for doubtful accounts,
- inventories and related reserves,
- goodwill and other intangible assets,
- income and other tax accruals,
- deferred tax asset valuation allowances,
- discounts and allowances,
- warranty obligations, and
- contingencies and litigation.

We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our assumptions and estimates may, however, prove to have been incorrect and our actual results may differ from these estimates under different assumptions or conditions. While we believe the assumptions and estimates we make are reasonable, any changes to our assumptions or estimates, or any actual results which differ from our assumptions or estimates, could have a material adverse effect on our financial position and operating results.

During the third quarter of 2007, we determined, based principally upon the recent decline in our current market capitalization to less than its June 30, 2007 book value for the preceding seven weeks prior to the end of the third quarter of 2007, as well as our decision to change our strategic direction to place any further development of the PARSEC® System on hold indefinitely, there was sufficient indication to require us to assess, in accordance with SFAS No. 142, whether any portion of our goodwill balance, which is recorded in both ImmunoVision and Delta, was impaired. Based primarily upon our estimate of forecasted discounted cash flows for each of these subsidiaries and our market capitalization, we determined that the carrying amount of the goodwill at each of Delta and ImmunoVision was in excess of its respective fair value. We concluded that all \$4,672,000 of the goodwill recorded at Delta and \$1,180,000 of the \$2,050,000 of goodwill recorded at

ImmunoVision was impaired. As a result, we recorded a noncash goodwill impairment charge to operations totaling \$5,852,000 during the third quarter of 2007. Additionally, a continued decline in our market capitalization could require us to record additional impairment charges in future periods for the remaining goodwill for ImmunoVision, which would have a material adverse effect on our financial position and operating results.

**The trend towards consolidation in the diagnostics industry may adversely affect us.**

The diagnostics industry has experienced considerable consolidation through mergers and acquisitions in the past several years. This consolidation trend may result in the remaining companies having greater financial resources and technological capabilities, thereby intensifying competition in the industry, which could have a material adverse effect on our business.

**Consolidation of our customers or the formation of group purchasing organizations could result in increased pricing pressure that could adversely affect our operating results.**

The health care industry has undergone significant consolidation resulting in increased purchasing leverage for customers and consequently increased pricing pressures on our business. Additionally, some of our customers have become affiliated with group purchasing organizations. Group purchasing organizations typically offer members price discounts on laboratory supplies and equipment if they purchase a bundled group of one supplier's products, which results in a reduction in the number of manufacturers selected to supply products to the group purchasing organization and increases the group purchasing organization's ability to influence its members' buying decisions. Further consolidation among customers or their continued affiliation with group purchasing organizations may result in significant pricing pressures and correspondingly reduce the gross margins of our business or may cause our customers to reduce their purchases of our products, thereby adversely affecting our business, prospects, operating results or financial condition.

Additionally, in Italy, and most other countries in Western Europe, our products are sold predominantly to public hospital laboratories, which are managed by government structures, either directly or indirectly. In most cases, our products are sold through tenders for multiple year periods. Due to the efforts exercised by many governments to contain healthcare costs, there has been a constant effort to consolidate laboratory units and, consequently, the bid process continues to become even more competitive. The containment of healthcare costs, consolidation of laboratory units or increase in the competitiveness of the bid process could adversely affect our business, prospects, operating results or financial condition.

**Reimbursement policies of third parties could affect the pricing and demand for our products.**

Our profitability may be materially adversely affected by changes in reimbursement policies of governmental and private third party payors. The products we market are purchased principally by healthcare providers that typically bill third party payors such as governmental programs (e.g., Medicare and Medicaid), private insurance plans and managed care plans, for healthcare services provided to their patients. Governmental reimbursement policies are subject to rapid and significant changes in the United States, at both the federal and state levels, and in other countries. Private third party payors are increasingly negotiating the prices charged for medical products and services. There can be no assurance that healthcare providers will not respond to such pressures by substituting competitors' products for our products. A third party payor may deny reimbursement if it determines that a device was not used in accordance with cost-effective treatment methods, was experimental, or for other reasons. There can be no assurance that our products will qualify for reimbursement by governmental programs in accordance with guidelines established by the Centers for Medicare and Medicaid Services, by state government payors or by commercial insurance carriers, or that reimbursement will be available in other countries.

**Cost containment measures and health care reform proposals could affect our ability to sell our products.**

Various legislative proposals, including proposals relating to the cost containment of healthcare products and the reimbursement policies of governmental and private third party payors, could materially impact the pricing and sale of our products. Reimbursement policies may not include our products. Even if reimbursement policies of third parties grant reimbursement status for a product, we cannot be sure that these reimbursement policies will remain in effect. Limits on reimbursement could reduce the demand for our products. The unavailability or inadequacy of third party reimbursement for our products could reduce or possibly eliminate demand for our products. We are unable to predict whether governmental authorities will enact additional legislation or regulation which will affect third party coverage and reimbursement that reduces demand for our products.

**Compliance with governmental regulation is critical to our business.**

The products we sell are subject to extensive regulation by numerous governmental and regulatory authorities in the United States, principally the FDA, and other countries. Such regulation includes the regulation of the approval, manufacturing and testing controls, labeling, marketing and sale of diagnostic devices. Failure to comply with these governmental regulations can result in fines, unanticipated compliance expenditures, interruptions of production and criminal prosecution.

The process of obtaining regulatory approval is rigorous, time consuming and costly. There is no assurance that necessary approvals will be attained on a timely basis, if at all, or at the anticipated cost. In addition, product approvals can be withdrawn if we fail to comply with regulatory standards or if unforeseen problems occur following initial marketing.

In addition, as a general matter, foreign regulatory requirements for medical devices are becoming increasingly stringent. "CE Marking" must be obtained for all medical devices commercially distributed in the European Union, even though the products may have received FDA clearance. In order to be commercially distributed throughout the European Union, certain of our products must bear the "CE Marking." All of the products that we currently sell throughout the European Union are in conformity with the applicable "CE" regulations under the In Vitro Diagnostics Directive. However, if in the future we lose the authorization to use the "CE Marking," we may not be able to sell our products in the European Union, which could have a material adverse effect on our business, prospects, operating results and financial condition.

Domestic and foreign regulations are subject to change and extensive changes in regulation may increase our operating expenses. The evolving and complex nature of regulatory requirements, the broad authority and discretion of regulatory authorities and the extremely high level of regulatory oversight result in a continuing possibility that we may be adversely affected by regulatory actions despite our efforts to maintain compliance with regulatory requirements. Delays in obtaining, or the inability to obtain, necessary domestic or foreign regulatory approvals, failures to comply with applicable regulatory requirements or extensive changes in regulation could have a material adverse effect on our business, prospects, operating results or financial condition.

**We are subject to a number of regulatory and contractual restrictions with respect to our Italian subsidiary.**

Delta, our wholly-owned subsidiary, is located in Italy. Our employment relations in Italy are governed by numerous regulatory and contractual requirements, including, among other things, national collective labor agreements and individual employer labor agreements. These arrangements address a number of specific issues affecting our working conditions, including, without limitation, hiring, work time, wages and benefits and termination of employment. We must make significant payments in order to comply with these requirements. The cost of complying with these requirements may materially adversely affect our business, prospects, operating results or financial condition. Additionally, Delta must comply with minimum capital requirements established

by Italian law. From time to time, we may utilize cash to assist Delta in maintaining its compliance with these capital requirements. There can be no assurance that Delta will be able to maintain its compliance with these capital requirements with or without our cash assistance. Under certain circumstances, during the time when Delta is utilizing cash assistance that we provide, the amount of such cash assistance may not be available for our use in other portions of our business. Furthermore, any cash assistance that we provide to Delta may not be repaid or distributed to us when expected, or at all. Any of these risks may adversely affect our liquidity or financial condition.

**Our products could fail to perform according to specification or prove to be unreliable, which could damage our customer relationships and industry reputation and result in lawsuits and loss of sales.**

Our customers require demanding specifications for product performance and reliability. Because the products we market are complex and often use state-of-the-art components, processes and techniques, undetected errors and design flaws may occur. Product defects result in higher product service, warranty and replacement costs and may cause serious damage to our customer relationships and industry reputation, all of which will negatively impact our sales and business. We may be subject to lawsuits if any of the products we market fails to operate properly or causes any ailment to be undiagnosed or misdiagnosed.

**We may be exposed to product liability claims and there can be no assurance of adequate insurance.**

Like all diagnostics companies, the testing, manufacturing and marketing of our products may expose us to product liability and other claims resulting from their use. If any such claims against us are successful, we may be required to make significant compensation payments and suffer the associated adverse publicity. Even unsuccessful claims could result in the expenditure of funds in litigation and the diversion of management time and resources. We believe that we maintain an adequate amount of product liability insurance, but there can be no assurance that our insurance will cover all existing and future claims or that we will be able to maintain existing coverage or obtain additional coverage at reasonable rates. If a claim is not covered or if our coverage is insufficient, we may incur significant liability payments that would have a material adverse effect on our business, operating results or financial condition.

**Damages to or disruptions at our facilities could adversely impact our ability to effectively operate our business.**

A portion of our facilities, as well as our corporate headquarters and other critical business functions, are located in Miami, Florida—an area subject to hurricane casualty risk. Although we have certain limited protection afforded by insurance, our business and earnings could be materially adversely affected in the event of a major windstorm.

**We have limited operating revenue and a history of primarily operational losses.**

For the year ended December 31, 2007, we recorded net revenues of \$20.0 million and net loss of \$10.4 million. For the year ended December 31, 2006, we recorded net revenues of \$19.5 million and net loss of \$2.8 million. Our principal source of short-term liquidity is, and during the past three years has been, existing cash and cash equivalents and marketable securities received as a result of cash received from the completion of the merger between b2bstores.com and the pre-merger IVAX Diagnostics, which we believe will be sufficient to meet our operating needs and anticipated capital expenditures over the next twelve months. For the long term, we intend to utilize principally existing cash and cash equivalents and marketable securities, as well as internally generated funds, which we anticipate will be derived primarily from our operations. There is, however, no assurance that existing cash and cash equivalents and marketable securities will satisfy all of our cash requirements and fund any losses from operations. Furthermore, there can be no assurance that we will be able to operate on a profitable basis or internally generate funds from our operations. If existing cash and cash equivalents and marketable securities are insufficient to finance operations or if we are unable to operate on a profitable basis or internally generate funds from our operations, then we may be required to issue securities or incur indebtedness to finance our operations or curtail or reduce our operations.

**We have invested a significant portion of our cash in marketable securities, including auction rate securities, which subjects us to liquidity risk and could require us to record an impairment charge if the fair value of these investments declines.**

At December 31, 2007, we had \$5.8 million of cash and cash equivalents and short-term marketable securities, and \$4.1 million of long-term marketable securities. We held \$1.9 million of the \$5.8 million of the cash and cash equivalents and short-term marketable securities, and all \$4.1 million of the long-term marketable securities, in AAA or Aaa rated auction rate securities at December 31, 2007. All of the auction rate securities in which we have invested are secured by pools of student loans, in excess of 90% of which are guaranteed under the Federal Family Education Loan Program ("FFELP"). We do not own, and have not invested in, any auction rate securities secured by mortgages or collateralized debt obligations.

Auction rate securities are floating rate debt securities with long-term maturities (generally between 20 and 30 years), the interest rates of which are reset periodically (typically every 28 or 35 days) through a competitive bidding process often referred to as a "Dutch auction." Despite the underlying long-term maturity of these securities, such securities were typically priced and subsequently traded as short-term investments because of their interest rate reset feature. The Dutch auction process has historically provided a liquid market for auction rate securities, as this mechanism generally allows existing investors to rollover their holdings and continue to own their respective securities at then existing market interest rates or to liquidate their holdings by selling their securities at par value. Recently, however, primarily due to the liquidity issues experienced in global credit and capital markets, many auctions for auction rate securities have failed and the sellers of such securities have been unable to liquidate their securities. A seller must then wait until the next successful auction to attempt to sell its auction rate securities, unless there is a secondary market for the particular securities. This means that if a seller needs to sell its investment in auction rate securities in order to achieve liquidity and obtain cash and the auction for such securities fails, then such a seller would not be able to obtain cash or achieve the liquidity typically provided by these short-term investments and may be required to hold its investment in such auction rate securities for an indefinite period of time up to the maturity of the underlying obligations. In the event that such a seller attempts to sell its investment in auction rate securities in a secondary market in order to achieve liquidity and obtain cash, because typically there is no secondary market for auction rate securities, such a seller may not be able to liquidate its investment or may only be able to do so for an unfavorable price. As a result of a failed auction, however, the auction rate securities will generally pay interest to the holder at a maximum or default rate defined by the securities' governing documents.

Subsequent to December 31, 2007, all \$6.0 million of our portfolio of marketable securities held at December 31, 2007 were sold through the Dutch auction process, with \$1.9 million of the proceeds then invested in other select short-term marketable security investments and \$4.1 million of the proceeds reinvested in auction rate securities. However, as described above, recent uncertainties in the global credit and capital markets have prevented sellers of auction rate securities, including us, from liquidating their holdings in auction rate securities. Since mid-February 2008, as described in Note 16 to our Consolidated Financial Statements, *Subsequent Event*, each of the remaining \$4.1 million of auction rate securities that we held experienced, and has continued to experience, failed auctions. As a result of these failed auctions, we have been unable to liquidate our investment and do not expect to be able to access our funds that are invested in these auction rate securities until a future auction of these securities is successful or a secondary market develops for these particular securities. This subjects us to liquidity risk. We cannot predict when future auctions related to these securities will be successful or when we will be able to otherwise liquidate our investment. If the auctions continue to fail for the auction rate securities in which we have invested, then we may not be able to sell such securities and obtain cash for an indefinite period of time up to the maturity date of the underlying obligations. While we believe that our existing cash and marketable securities will provide sufficient funds to finance our operations for the next twelve months, if we require additional liquidity, then we may be required to issue debt or equity securities or incur indebtedness to finance our operations or curtail or reduce our operations.

We will continue to monitor the value of our auction rate securities each reporting period for a possible impairment if a decline in fair value occurs. On March 31, 2008, we received notification that the investment

bank holding our auction rate securities will value these securities at approximately \$3.9 million, or 95.43% of par value, based upon an internal valuation model developed by the investment bank. This valuation model considered for each security such factors as liquidity, credit rating, underlying collateral, final maturity and applicable insurance when estimating value. Based upon this information, we may recognize a temporary reduction to our shareholders' equity in our financial statements as of and for the quarter ending March 31, 2008. If we determine that it is necessary to lower the carrying value of these auction rate securities to reflect their prevailing fair value, then we would be required to record a corresponding impairment charge which could materially and adversely affect our financial condition or results of operations.

**If we fail to collect our accounts receivable, our operating results could be materially adversely affected.**

We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. As of December 31, 2007 and 2006, our accounts receivable were \$7.3 million and \$8.6 million, respectively, and our allowance for doubtful accounts was \$1.1 million and \$1.1 million, respectively. As of December 31, 2007 and 2006, \$5.2 million and \$6.2 million, respectively, of our accounts receivable were due in Italy, and \$0.8 million and \$0.7 million, respectively, of our allowance for doubtful accounts related to Italian accounts receivable. Approximately 80% of Delta's revenue generated from customers in Italy is revenue from government owned hospitals and the remaining 20% of revenue is from private laboratories. As of December 31, 2007 and 2006, 58.3% and 66.2%, respectively, of our net accounts receivable were due from hospitals and laboratories controlled by the Italian government. Accordingly, we are subject to credit risk if the Italian government does not, or is not able to, pay amounts owed to us.

In many instances, our receivables in Italy, while currently due and payable, take in excess of a year to collect and, although untimely, most customers have historically paid the amounts they owe. Nevertheless, there is no assurance that we will collect the outstanding accounts receivable or that the allowance for doubtful accounts will be adequate. The failure to collect outstanding receivables, whether relating to Italy, the United States or elsewhere, could have a material adverse effect on our business, prospects, operating results or financial condition. If the financial condition of our customers was to deteriorate, resulting in an impairment of their ability to make payments, then we may be required to make additional allowances, which would adversely affect our operating results in the period in which the determination or allowance is or was made.

Additionally, we periodically receive payments based upon negotiated agreements with governmental regions in Italy, acting on behalf of hospitals located in the region, in satisfaction of previously outstanding accounts receivable balances. We may anticipate collection of these amounts through a payment as described above, and, therefore, not provide an allowance for doubtful accounts for these amounts. Additional payments by governmental regions in Italy are possible, and, as a result, we may consider the potential receipt of those payments in determining our allowance for doubtful accounts. If contemplated payments are not received, if existing agreements are not complied with or cancelled or if we require additional allowances, then our operating results could be materially adversely affected during the period in which the determination to increase the allowance for doubtful accounts is or was made.

**Political and economic instability and foreign currency fluctuations may adversely affect the revenues generated by our foreign operations.**

We have a significant wholly-owned subsidiary, Delta, located in Italy. For the years ended December 31, 2007 and 2006, Delta represented 31.3% and 33.1%, respectively, of our net revenues. Conducting an international business inherently involves a number of difficulties, risks and uncertainties, such as:

- export and trade restrictions,
- inconsistent and changing regulatory requirements,
- tariffs and other trade barriers,
- cultural issues,
- longer payment cycles,

- problems in collecting accounts receivable,
- political instability,
- local economic downturns,
- seasonal reductions in business activity in Europe during the traditional summer vacation months, and
- potentially adverse tax consequences.

Any of the above factors may materially and adversely affect our business, prospects, operating results or financial condition.

For the years ended December 31, 2007 and 2006, 31.3% and 33.1%, respectively, of our net revenues were generated in currencies other than the United States dollar. Fluctuations in the value of foreign currencies relative to the United States dollar affect our operating results. For instance, if the United States dollar strengthens relative to foreign currency, then our earnings generated in foreign currency will, in effect, decrease when converted into United States dollars, which could have a material and adverse effect on our operating results and cash flows. We do not use financial derivatives to hedge exchange rate fluctuations.

**Our potential acquisitions may reduce our earnings, be difficult for us to combine into our operations or require us to obtain additional financing.**

In the ordinary course of our business, we evaluate potential business acquisition opportunities that we anticipate will provide new product and market opportunities, benefit from and maximize our existing assets and add critical mass. We often incur significant expenses in connection with our evaluation of potential business acquisition opportunities. However, we may not be successful in finding or consummating any acquisitions, and any acquisitions we make may expose us to additional risks and may have a material adverse effect on our operating results. Any acquisitions we make may fail to accomplish our strategic objectives, may not be successfully combined with our operations or may not perform as expected. In addition, although we generally seek acquisitions that we believe will be accretive to our per share earnings, based on current acquisition prices in the industry, our acquisitions could initially reduce our earnings and add significant intangible assets and related amortization charges. Our acquisition strategy may require us to obtain debt or equity financing, resulting in increased leverage or increased debt obligations, as compared to equity, and the dilution of our stockholders' ownership of us. We may not be able to finance acquisitions on terms satisfactory to us.

**The impact of new accounting principles could have a material adverse effect on our operating results or financial condition.**

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS No. 123 (revised 2004), *Share-Based Payment*, or SFAS 123(R), which addresses the accounting for transactions in which an entity exchanges its equity instruments for goods or services. This Statement focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. This Statement requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based upon their fair values. The future impact of this Statement will depend on levels of share-based payments in the future. Our adoption of the fair value recognition provisions of this Statement resulted in a cumulative effect adjustment of \$0.2 million in 2006, which reflects the change in classification of certain options granted in March 2001 from an equity award grant to a liability award. The resulting liability was reduced to \$0 as of December 31, 2007. Our adoption of the fair value recognition provisions of this Statement and other new accounting principles adopted in the future may have a material adverse effect on our financial condition or operating results.

**We will be exposed to risks relating to evaluations of internal control over financial reporting required by Section 404 of the Sarbanes-Oxley Act of 2002.**

We anticipate spending a substantial amount of management time and resources to comply with changing laws, rules, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, regulations promulgated by the Securities and Exchange Commission and rules promulgated by the American Stock Exchange.

In this Annual Report on Form 10-K, our management has provided an assessment as to the effectiveness of our internal control over financial reporting. However, because we meet the definition of a non-accelerated filer, under the current rules and regulations of the Securities and Exchange Commission, our management's assessment is furnished to, rather than filed with, the Securities and Exchange Commission, and our independent registered public accounting firm was not required to provide, and has not provided, in this Annual Report on Form 10-K an attestation as to our management's assessment. In our Annual Report on Form 10-K for the year ending December 31, 2008 and for each fiscal year thereafter, our management will be required to provide an assessment as to the effectiveness of our internal control over financial reporting and our independent registered public accounting firm will be required to provide an attestation as to our management's assessment, which assessment and attestation will be filed with the Securities and Exchange Commission. The processes required by Section 404 are relatively new to us. Accordingly, we may encounter problems or delays in completing our obligations and receiving an unqualified report on our internal control over financial reporting by our independent registered public accounting firm.

While we believe that we will be able to timely meet our obligations under Section 404, there is no assurance that we will do so. If we are unable to timely comply with Section 404, our management is unable to provide any required future assessment as to the effectiveness of our internal control over financial reporting or our independent registered public accounting firm is unable to attest to that assessment, the price of our common stock may be adversely affected. Even if we timely meet the requirements of Section 404, it is possible that our independent registered public accounting firm will advise us that they have identified significant deficiencies and/or material weaknesses, which may also adversely affect the price of our common stock.

**Substantially all of our cash and cash equivalents and marketable securities are held at a single brokerage firm.**

Substantially all of our cash and cash equivalents and short-term marketable securities are presently held at one international securities brokerage firm, UBS. Accordingly, we are subject to credit risk if this brokerage firm is unable to repay the balance in the account or deliver our securities or if the brokerage firm should become bankrupt or otherwise insolvent. Any of the above events could have a material and adverse effect on our business and financial condition.

**Teva, indirectly through its wholly-owned IVAX subsidiary, controls our company.**

Teva, indirectly through its wholly-owned IVAX subsidiary, owns approximately 72.3% of the issued and outstanding shares of our common stock. Under our certificate of incorporation, on issues for which our stockholders are eligible to vote, the affirmative vote of a majority of the shares represented at a meeting, in person or by proxy, and entitled to vote, is required to approve an action. Consequently, Teva can unilaterally approve actions that require stockholder approval and elect directors acceptable to it based on its share ownership.

**We may have conflicts of interest with Teva.**

Conflicts of interest may arise between Teva and us in a number of areas relating to past matters with IVAX and ongoing matters with Teva or its affiliates, including, without limitation, labor, tax, employee benefits, indemnification, intellectual property, employee retention and recruiting, major business combinations, Teva's sale or distribution of all or any portion of its ownership interest in us, the nature, quality and pricing of the

administrative services Teva provides or IVAX has provided to us, and business opportunities that might be attractive to both Teva and us. Teva may decide to compete with us in the future, which would create an additional conflict of interest. Furthermore, two members of our board of directors are employees of Teva, and one member of our board of directors is a former employee of Teva. For as long as Teva controls us, Teva will be able to require us to agree to amend any agreements we have with IVAX or have or will have with Teva or its affiliates, even if those amendments are less favorable to us than the current terms of any such agreement. We cannot guarantee that any conflicts that may arise will be resolved in a matter that is favorable to us. Additionally, even if we do resolve such conflicts, the resolutions may be less favorable to us than it would be if we were dealing with an unaffiliated third party.

Many of our directors have, and certain of our officers and employees may have, a substantial amount of their personal financial portfolios in Teva ADRs. Potential conflicts of interests may arise if those directors or officers are faced with decisions that could have different implications for Teva and us and, in some instances, these decisions could be disadvantageous to us and advantageous to Teva.

Any of the above factors may materially and adversely affect our business, prospects, operating results or financial condition.

**We have limited rights to the “IVAX” name and may be required to change our name in the future.**

In 2001, we entered into a use of name license agreement with IVAX whereby IVAX granted us a non-exclusive, royalty free license to use the name “IVAX.” IVAX may terminate this license at any time upon 90 days’ written notice. There can be no assurance that IVAX will not terminate this license agreement. Upon termination of this license agreement, we are required to take all steps reasonably necessary to change our name as soon as practicable. The termination of this license agreement could have a material adverse effect on our business, prospects, operating results or financial condition.

**Our stock has a limited trading volume and a number of internal and external factors have caused, and may continue to cause, the market price of our stock to be volatile.**

Our common stock has been listed and traded on the American Stock Exchange since March 15, 2001. As a result of Teva, through its wholly-owned IVAX subsidiary, owning approximately 72.3% of the issued and outstanding shares of our common stock, we have a limited non-affiliate market capitalization. As a result, our common stock has a limited trading volume, which makes it more difficult for our stockholders to sell their shares.

Additionally, the market prices for securities of companies engaged in the healthcare field, including us, have been volatile. Many factors, including many factors over which we have no control, may have a significant impact on the future market price of our common stock, including, without limitation:

- announcements by us and our competitors of technological innovations, new commercial products or significant contracts or business acquisitions,
- period-to-period changes in our financial results,
- market acceptance of existing or new products,
- the financial results of, and announcements made by and actions taken by, Teva, and
- changes in general conditions in the economy, financial markets or healthcare industry.

**The issuance of preferred stock or additional shares of common stock could adversely affect the rights of the holders of shares of our common stock.**

Our board of directors is authorized to issue up to 5,000,000 shares of preferred stock without any further action on the part of our stockholders. Currently, we have no shares of preferred stock outstanding. In the event that we issue preferred stock in the future that has preference over the common stock with respect to payment of dividends or upon our liquidation, dissolution or winding up, the rights of holders of shares of our common stock may be adversely affected. In addition, the ability of our board of directors to issue shares of preferred stock without any further action on the part of our stockholders may impede a takeover of us and may prevent a transaction that is favorable to our stockholders.

**CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS**

We have made forward-looking statements, which are subject to risks and uncertainties, in this Annual Report on Form 10-K. Forward-looking statements may be preceded by, followed by or otherwise include the words "may," "will," "believes," "expects," "anticipates," "intends," "plans," "estimates," "projects," "could," "would," "should," or similar expressions or statements that certain events or conditions may occur. Actual results, performance or achievements could differ materially from those contemplated, expressed or implied by these forward-looking statements. These forward-looking statements are based largely on our expectations and the beliefs and assumptions of our management and on the information currently available to it and are subject to a number of risks and uncertainties, including, but not limited to, the risks and uncertainties associated with:

- economic, competitive, political, governmental and other factors affecting us and our operations, markets and products;
- the success of technological, strategic and business initiatives, including our automation strategy and our development and pending commercial release of our upgraded version of the Mago® Plus instrument, named the Mago® 4;
- our ability to successfully implement the change in strategic direction to place any further development of the PARSEC® System on hold indefinitely and to focus on the development of the Mago® 4 as a platform for marketing our kits;
- the impact of the change in strategic direction described above on our international activities associated with the PARSEC® System and on our financial condition, operating results and cash flows;
- our ability to expand or maintain our customer base in light of the change in strategic direction described above and the impact on our financial condition, operating results and cash flows;
- the impact of the change in strategic direction described above on the judgments and estimates we have made with respect to our intangible assets relating to our hepatitis technology product license and on our financial condition, operating results and cash flows;
- our ability to receive regulatory approval for the Mago® 4 when expected, or at all;
- the ability of the Mago® 4 to be available when expected, or at all;
- the ability of the Mago® 4 to perform as expected;
- the impact of the anticipated timing of the commercial release of the Mago® 4 on the judgments and estimates we have made with respect to our inventory, property and equipment, equipment on lease, goodwill and product intangibles and on our financial condition, operating results and cash flows;
- the impact on our financial condition and operating results of making or changing judgments and estimates regarding our inventory, property and equipment, equipment on lease, goodwill and product intangibles as a result of future design changes to, or the development of improved instrument versions of, the Mago® 4 or as a result of future demand for the Mago® 4;
- the ability of the Mago® 4 to be a source of revenue growth for us;

- our ability to receive financial benefits or achieve improved operating results after the commercial release of the Mago® 4;
- the ability of the Mago® 4 to be a factor in our growth;
- the ability of the Mago® 4 to expand the menu of test kits we offer;
- making the Mago® 4 our primary platform for marketing our kits;
- our ability to successfully market the Mago® 4;
- our customers' integration of the Mago® 4 into their operations;
- constantly changing, and our compliance with, governmental regulation;
- the impact of our adoption or implementation of new accounting statements and pronouncements on our financial condition and operating results;
- our limited operating revenues and history of primarily operational losses;
- our ability to collect our accounts receivable and the impact of making or changing judgments and estimates regarding our allowances for doubtful accounts on our financial condition and operating results;
- our ability to utilize our net operating losses and the impact of making or changing judgments and estimates regarding our deferred tax liabilities and our valuation allowances and reserves against our deferred tax assets on our financial condition and operating results;
- the impact of making or changing judgments and estimates regarding our goodwill, including the remaining goodwill recorded at ImmunoVision, and other intangible assets on our financial condition and operating results;
- our ability to achieve cost advantages from our own manufacture of instrument systems, reagents and test kits;
- our ability to grow beyond the autoimmune and infectious disease markets and to expand into additional diagnostic test sectors;
- our ability to obtain product technology from the Italian diagnostics company that would enable us to manufacture our own hepatitis products;
- our ability to receive authorization for "CE Marking" for our own hepatitis products in the European Union when expected, or at all;
- our ability to internally manufacture our own hepatitis products and raw materials for these products and to become competitive in markets outside of the United States;
- our ability to derive revenue from our manufacture and sale of our own hepatitis products;
- our agreements with Teva, IVAX, third party distributors and key personnel;
- consolidation of our customers affecting our operations, markets and products;
- reimbursement policies of governmental and private third parties affecting our operations, markets and products;
- price constraints imposed by our customers and governmental and private third parties;
- our ability to increase the volume of our reagent production to meet increased demand;
- our ability to consummate potential acquisitions of businesses or products;
- our ability to integrate acquired businesses or products;
- our ability to sell the current location of our Miami facility and to acquire a new location to which to relocate it;

- protecting our intellectual property;
- political and economic instability and foreign currency fluctuation affecting our foreign operations;
- the amount of severance costs that will eventually be paid in connection with the termination of certain of Delta's employees;
- the effects of utilizing cash to assist Delta in maintaining its compliance with capital requirements established by Italian law;
- our ability to liquidate our investment in auction rate securities or access our funds which are invested in auction rate securities, including, without limitation, the risk that we may not be able to sell these securities and obtain cash for an indefinite period of time up to the maturity date of the underlying obligations in the event that auctions continue to fail for these securities;
- our determinations regarding the carrying value of the auction rate securities we hold and the impact on our financial condition and results of operations of an impairment charge which we may be required to record in the event that we determine that it is necessary to lower the carrying value of these securities to reflect their prevailing fair value;
- the holding of substantially all of our cash and cash equivalents and marketable securities at a single brokerage firm, including risks relating to the bankruptcy or insolvency of such brokerage firm;
- litigation regarding products, distribution rights, intellectual property rights, product liability and labor and employment matters;
- our ability to comply with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002;
- our ability, when required, to receive an unqualified report on our internal control over financial reporting by our independent registered public accounting firm in connection with Section 404 of the Sarbanes-Oxley Act of 2002;
- voting control of our common stock by Teva;
- conflicts of interest with Teva, IVAX and with our officers, directors and employees; and
- other factors discussed elsewhere in this Annual Report on Form 10-K.

Many of these factors are beyond our control.

#### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

Not applicable.

#### **ITEM 2. PROPERTIES**

Our corporate headquarters are located in Miami, Florida. Our corporate headquarters share facilities with Diamedix, which owns approximately 56,000 square feet of buildings at its facility in Miami, Florida. From this facility, Diamedix conducts research and development of in vitro diagnostic products, reagent kit manufacturing, marketing and corporate management activities. Delta leases approximately 56,000 square feet of industrial space in Pomezia, Italy, which houses warehouse, production and commercial office facilities. This facility is where our proprietary instrumentation is manufactured. ImmunoVision leases approximately 5,700 square feet of commercial space in Springdale, Arkansas.

We believe our facilities are in satisfactory condition, are suitable for their intended use and, in the aggregate, have capacities in excess of those necessary to meet our present needs.

**ITEM 3. LEGAL PROCEEDINGS**

We are involved in various legal claims and actions and regulatory matters and other notices and demand proceedings arising in the ordinary course of business. While it is not possible to predict or determine the outcome of these proceedings, in the opinion of management, based on a review with legal counsel, any losses resulting from such legal proceedings would not have a material adverse impact on our financial position, results of operations or cash flows.

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

No matters were submitted to a vote of security holders during the quarter ended December 31, 2007.

**PART II**

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

Our common stock is listed on the American Stock Exchange and trades under the symbol “IVD.”

As of the close of business on March 26, 2008, there were approximately 46 holders of record of our common stock.

The following table sets forth the high and low sales prices of a share of our common stock for each quarter in 2007 and 2006, as reported by the American Stock Exchange:

<u>2007</u>	<u>High</u>	<u>Low</u>
Fourth Quarter .....	\$0.71	\$0.45
Third Quarter .....	1.09	0.60
Second Quarter .....	1.29	0.88
First Quarter .....	1.47	0.95
 <u>2006</u>		
Fourth Quarter .....	\$1.70	\$1.20
Third Quarter .....	2.08	1.25
Second Quarter .....	3.30	1.61
First Quarter .....	3.80	3.15

We did not declare or pay cash dividends on our common stock during 2007 or 2006, and we do not intend to pay any cash dividends in the foreseeable future.

**ITEM 6. SELECTED FINANCIAL DATA**

Not required.

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

The following discussion and analysis should be read in conjunction with our Consolidated Financial Statements and the related Notes to Consolidated Financial Statements on pages 40 to 66 of this Annual Report on Form 10-K.

### OVERVIEW

We are the parent corporation of the following three subsidiaries:

- Delta Biologicals, S.r.l.;
- Diamedix Corporation; and
- ImmunoVision, Inc.

Through these subsidiaries, we develop, manufacture, and market diagnostic test kits, or assays, and automated systems that are used to aid in the detection of disease markers primarily in the areas of autoimmune and infectious diseases. In addition to diagnostic kits, we also design and manufacture laboratory instruments that perform the tests and provide fast and accurate results, while reducing labor costs. We also develop, manufacture, and market raw materials, such as antigens used in the production of diagnostic kits.

Our management reviews financial information, allocates resources and manages the business as two segments defined by geographic region. One segment—the domestic region—contains Diamedix and ImmunoVision, our subsidiaries located in the United States and corporate operations. Our other segment—the Italian region—contains Delta, our subsidiary located in Italy.

Diamedix' products are sold in the United States through Diamedix' sales force. Diamedix markets 50 assays that the FDA has cleared. Most of these assays are sold under the trade name immunosimplicity® and are available to be run in conjunction with the Mago® Plus and Aptus® systems.

ImmunoVision develops, manufactures, and markets autoimmune reagents and research products for use by research laboratories and commercial diagnostic manufacturers. These manufacturers (including Diamedix) use these antigens to produce autoimmune diagnostic kits.

From its facility located in Pomezia, Italy, Delta develops and manufactures scientific and laboratory instruments, including its proprietary Mago® Plus and Aptus® systems, which include hardware, reagents, and software. The Mago® Plus and Aptus® systems, in association with over 200 specific ELISA-based assays acquired from Diamedix and third parties, as well as a complete line of allergy products, are sold directly in Italy through Delta's independent sales force and sales representatives, most of whom work exclusively for Delta. Delta also sells in Italy other diagnostic products manufactured by third parties. Approximately 80% of Delta's revenue generated from customers in Italy is revenue from government owned hospitals and the remaining 20% is revenue from private laboratories. Thus, sales in Italy are heavily concentrated in the public sector. Delta also serves as the distribution and support center for selling these same products to distributors located in other European and international markets outside Italy.

## MAJORITY STOCKHOLDER

On July 25, 2005, IVAX, which then owned approximately 72.3% of the outstanding shares of our common stock, entered into a definitive agreement and plan of merger with Teva providing for IVAX to be merged into a wholly-owned subsidiary of Teva. On January 26, 2006, the merger was consummated and IVAX became a wholly-owned subsidiary of Teva for an aggregate purchase price of approximately \$3.8 billion in cash and 123 million Teva ADRs. The transaction was reported to be valued, for accounting purposes, at \$7.9 billion, based on the value of the Teva ADRs during the five trading day period commencing two trading days before the date of the definitive agreement and plan of merger. As a result of the merger, Teva now, indirectly through its IVAX subsidiary, owns approximately 72.3% of the outstanding shares of our common stock.

## RESULTS OF OPERATIONS

### YEAR ENDED DECEMBER 31, 2007 COMPARED TO THE YEAR ENDED DECEMBER 31, 2006

#### OVERVIEW

Net losses totaled \$10,434,000 in 2007 and \$2,809,000 in 2006. Operating losses were \$11,318,000 in 2007 and \$2,874,000 in 2006. Net loss and loss from operations significantly increased in 2007 compared to 2006 due to a write-off of goodwill of \$5,852,000, the write-off of PARSEC® System related assets totaling \$1,674,000, and severance costs of \$1,998,000 included in general and administrative expenses that were incurred in connection with management and other personnel changes. The net loss and loss from operations in 2006 included the write-off of certain PARSEC® System related assets totaling \$509,000. The net loss in 2006 also included the \$201,000 cumulative effect of a change in accounting principle as a result of our adoption of SFAS No. 123(R) as of January 1, 2006.

The write-off of goodwill in 2007 included the write-off of the entire balance of goodwill related to our Italian operations of \$4,672,000, as well as \$1,180,000 of the \$2,050,000 of goodwill recorded at ImmunoVision, a member of our domestic segment. These goodwill write-offs were principally the result of an impairment analysis performed due to the recent significant decline in our market capitalization to below our book value, as well as the recent decision to change our strategic direction to focus on the development of the new Mago® 4 instrument, the upgraded version of our existing MAGO® Plus instrument, as a platform for marketing our kits and to place any further development of the PARSEC® system on hold indefinitely. This change in strategic direction also resulted in the \$1,674,000 write-off of PARSEC® System related assets included in inventory, property and equipment and equipment on lease and other current assets in 2007.

Net revenues increased \$453,000 from 2006 to \$19,976,000 in 2007 as a result of an increase of \$662,000 in net revenues from domestic operations offset by a decrease of \$209,000 in net revenues from Italian operations. Gross profit increased \$511,000 to \$11,577,000, or 58.0% of net revenues, in 2007 from \$11,066,000, or 56.7% of net revenues, in 2006. Operating expenses increased in 2007 compared to 2006 as a result of the write-offs of goodwill and PARSEC® System related assets, and the severance costs included in general and administrative expenses described above. Additionally, the decrease in selling expenses was partially offset by increases in research and development expenses and the other components of general and administrative expenses. Other income increased \$164,000 and interest income decreased \$29,000 in 2007 compared to 2006. Additionally, we had a tax benefit of \$329,000 in 2007 compared to a tax provision of \$153,000 in 2006. This difference was due to the tax benefit resulting from the required adjustment of our deferred tax liability related to tax deductible goodwill recorded as a result of the 2007 write-off of a portion of the goodwill recorded at ImmunoVision.

## NET REVENUES AND GROSS PROFIT

	2007	2006	Period over Period Increase (Decrease)
Net Revenues			
Domestic .....	\$13,727,000	\$13,065,000	\$ 662,000
Italian .....	6,249,000	6,458,000	(209,000)
Total .....	19,976,000	19,523,000	453,000
Cost of Sales .....	8,399,000	8,457,000	(58,000)
Gross Profit .....	\$11,577,000	\$11,066,000	\$ 511,000
% of Total Net Revenues .....	58.0%	56.7%	

Net revenues in 2007 increased \$453,000, or 2.3%, from 2006. This increase was comprised of an increase in net revenues from domestic operations of \$662,000 offset by a decrease in net revenues from Italian operations of \$209,000. Domestic net revenues in 2007 increased by 5.1% from 2006, primarily due to volume increases in reagent sales to instrumentation customers. The 3.2% decline in net revenues from Italian operations includes the effect of an increase in revenue of \$520,000 due to currency fluctuations of the United States dollar relative to the Euro as further discussed in "Currency Fluctuations" below. As measured in Euros, Italian net revenues declined by 11.3% compared to 2006 due principally to the loss of a significant customer and certain smaller customers and the continuing trend of sales price reductions. Gross profit in 2007 increased \$511,000, or 4.6%, from the prior year. The principal factors in the increase in gross profit, and the increase in gross profit as a percentage of net revenues to 58.0% in 2007 from 56.7% in 2006, were the improved gross margin on domestic sales of reagent kits, a reduction in equipment on lease amortization and reduced costs at Delta on products purchased from the United States due to exchange rate fluctuations.

## OPERATING EXPENSES

	2007	% of Revenue	2006	% of Revenue	Period over Period Increase (Decrease)
Selling Expenses					
Domestic .....	\$ 3,123,000	15.6%	\$ 3,609,000	18.5%	\$ (486,000)
Italian .....	2,363,000	11.9%	2,275,000	11.7%	88,000
Total .....	5,486,000	27.5%	5,884,000	30.1%	(398,000)
General and Administrative .....	7,730,000	38.7%	5,652,000	29.0%	2,078,000
Research and Development .....	2,152,000	10.8%	1,895,000	9.7%	257,000
Impairment of Goodwill .....	5,852,000	29.3%	—	29.0%	5,852,000
Write-off of PARSEC® Related Assets .....	1,674,000	8.4%	509,000	2.6%	1,165,000
Total Operating Expenses .....	\$22,894,000	114.6%	\$13,940,000	71.4%	\$8,954,000

We recorded two significant noncash charges in operating expenses during 2007, the largest of which was a goodwill impairment charge of \$5,852,000 recorded during the third quarter of 2007. The determination to analyze our recorded goodwill balance for impairment was based principally upon the decline in our market capitalization to less than our June 30, 2007 book value for the preceding seven weeks prior to the end of the third quarter, as well as the decision that we made during the third quarter of 2007 to change our strategic direction to place any further development of the PARSEC® System on hold indefinitely. Based primarily upon our estimate of forecasted discounted cash flows and our market capitalization, we determined that the carrying amount of the goodwill at our Italian subsidiary, Delta Biologicals, and at ImmunoVision, a member of our domestic segment, was in excess of its respective fair value. We concluded that all \$4,672,000 of the goodwill recorded at Delta Biologicals and \$1,180,000 of the \$2,050,000 of goodwill recorded at ImmunoVision was impaired. As a result, we recorded a noncash goodwill impairment charge to operations totaling \$5,852,000 during the third quarter of 2007. No goodwill impairment charge was recorded during 2006.

The other noncash charge during 2007 was a write-off of PARSEC® System related assets included in inventory, property and equipment, equipment on lease and other current assets totaling \$1,674,000 as a result of our decision that we intend to change our strategic direction to focus on the development of the new Mago® 4 instrument, the upgraded version of our existing Mago® Plus instrument, as a platform for marketing our kits and to place any further development of the PARSEC® System on hold indefinitely. Our 2006 operating expenses included a \$509,000 write-off of certain PARSEC® System related assets and inventory recorded when we determined that certain of these assets were not compatible with anticipated future instrument versions. While performing the analysis that resulted in this determination, we became aware of, and included in that adjustment, errors in prior periods totaling \$154,000 principally related to still usable fixed assets relating to the PARSEC® System that had not been properly depreciated.

General and administrative expenses increased \$2,078,000 in 2007 compared to 2006 principally due to severance costs of \$1,998,000 accrued as a result of anticipated costs associated with management and other personnel changes that occurred, or were being negotiated during, the fourth quarter of 2007. Included in this amount is the effect of a separation agreement and general release negotiated with Giorgio D'Urso in connection with his resignation, effective January 10, 2008, as our President and Chief Executive Officer and as a member of our Board of Directors. Pursuant to this separation agreement, we paid Mr. D'Urso a one-time lump-sum payment of \$495,000 and terminated his then existing employment agreement that provided for Mr. D'Urso to serve as our President and Chief Executive Officer until February 24, 2010 and to receive a minimum annual base salary of \$348,519. The remaining severance costs principally include estimated costs in connection with the terminations of selected employees of Delta Biologicals, our Italian subsidiary. Amounts that will eventually be paid in Italy will be subject to negotiations with the affected individuals and are subject to, and in some cases governed by, national collective and individual labor agreements existing in Italy. Variations in general and administrative expenses were also the result of increases in domestic professional fees and the reduction in general and administrative expenses reported in 2006 as the result of the fair value adjustment of the stock option liability award described in Note 2, *Stock-Based Compensation*, partially offset by lower insurance costs and bad debt expenses. Other variations in 2007 operating expenses include a decrease in selling expenses of \$398,000 compared to 2006 as a result of a reduction in domestic selling expenses, principally due to lower labor, travel and instrument service expenses. Excluding the effects of the fluctuation in exchange rates, Italian selling expenses decreased 4.8% in 2007 compared to 2006 principally due to one-time costs recorded in 2006. Research and development expenses increased \$257,000 in 2007 compared to 2006. Excluding the effects of exchange fluctuations, Italian research and development expenses increased to 1,129,000 Euro in 2007 due to increases resulting from the hepatitis technology product license and PARSEC® System and Mago® 4 instrumentation development projects in Italy. Domestic research and development expenses decreased from \$739,000 in 2006 to \$604,000 in 2007. The future level of research and development expenditures, which is expected to be less than our historical levels due to our decision to place any further development of the PARSEC® System on hold indefinitely, will depend on, among other things, the outcome of ongoing testing of products and instrumentation under development, delays or changes in government required testing and approval procedures, technological and competitive developments, strategic marketing decisions and liquidity.

## LOSS FROM OPERATIONS

Losses from operations were \$11,318,000 in 2007 compared to \$2,874,000 in 2006. The loss from operations in 2007 was composed of a loss from Italian operations of \$9,304,000, which included charges of \$4,672,000 for goodwill impairment, \$1,430,000 for the write-off of PARSEC® System related assets and \$1,413,000 of the recorded severance costs described above, and a loss from domestic operations of \$1,999,000, which included charges of \$1,180,000 for goodwill impairment, \$244,000 for the write-off of PARSEC® System related assets and \$585,000 of the recorded severance costs described above. The loss from operations in 2006 was composed of a loss from Italian operations of \$2,087,000, which included the write-off of \$509,000 of certain assets relating to the PARSEC® System, and a loss from domestic operations of \$824,000. Domestic operations include corporate expenditures, including costs relating to our status as a public company.

## **OTHER INCOME, NET**

Interest income decreased \$29,000 to \$435,000 in 2007 from \$464,000 in 2006 due principally to lower average cash balances and investments that were invested during 2007. Other income, net totaled \$120,000 during 2007, compared to other expense, net of \$44,000 in 2006. Amounts included in other income (expense), net in 2007 and 2006 were primarily net foreign currency gains or losses on transactions, particularly by our Italian subsidiary, which were denominated in currencies other than the subsidiary's functional currency.

## **INCOME TAX PROVISION (BENEFIT)**

We recorded an income tax benefit of \$329,000 during 2007 and an income tax provision of \$153,000 during 2006. The tax benefit in 2007 relates to the domestic deferred tax benefit, recorded due to the adjustment of our deferred tax liability relating to tax deductible goodwill, recognized as a result of the goodwill impairment charge taken at ImmunoVision. The current tax provisions in 2007 and 2006 relate to Italian local income taxes based upon applicable statutory rates effective in Italy. No current domestic tax provision or benefit was recorded in 2007 or 2006 as we have a net operating loss and a full valuation allowance against the domestic net deferred income tax assets.

## **CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE**

We recorded a cumulative effect of a change in accounting principle of \$201,000 in 2006 as a result of the change in classification of certain options granted in March 2001 from an equity award grant to a liability award in accordance with the adoption of SFAS 123(R) on January 1, 2006. A cumulative effect of a change in accounting principle was not recorded during 2007. The basic and diluted per common share effect of this change in accounting principle was \$(0.01) in 2006. As of December 31, 2006, the resulting liability was reduced to \$23,000, and the fair value adjustment of \$178,000 was reported as a reduction of general and administrative expenses. As of December 31, 2007, the resulting liability has been reduced to \$0, and the fair value adjustment of \$23,000 has been reported as a reduction of general and administrative expenses.

## **NET LOSS**

We generated a net loss of \$10,434,000 in 2007 compared to a net loss of \$2,809,000 in 2006. Our net loss per basic and diluted common share was \$0.38 in 2007 compared to net loss per basic and diluted common share of \$0.10 in 2006. The net losses in 2007 and 2006 resulted primarily from the various factors discussed above. See *Note 2, Summary of Significant Accounting Policies*, in the Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for a description of the calculation of loss per share and our application of SAB 108 using the cumulative effect transition method.

## **LIQUIDITY AND CAPITAL RESOURCES**

At December 31, 2007, our working capital was \$9,732,000 compared to \$18,365,000 at December 31, 2006. Cash and cash equivalents totaled \$3,901,000 at December 31, 2007 and \$1,996,000 at December 31, 2006. Short-term marketable securities were \$1,925,000 at December 31, 2007 and \$6,650,000 at December 31, 2006. Long-term marketable securities were \$4,100,000 at December 31, 2007, and we had no long-term marketable securities at December 31, 2006.

In the years ended December 31, 2007 and 2006, available cash was typically invested in auction rate securities. Auction rate securities are floating rate debt securities with long-term maturities (generally between 20 and 30 years), the interest rates of which are reset periodically (typically every 28 or 35 days) through a competitive bidding process often referred to as a "Dutch auction." Despite the underlying long-term maturity of these securities, such securities were typically priced and subsequently traded as short-term investments because

of their interest rate reset feature. The Dutch auction process has historically provided a liquid market for auction rate securities, as this mechanism generally allows existing investors to rollover their holdings and continue to own their respective securities at then existing market interest rates or to liquidate their holdings by selling their securities at par value. Recently, however, primarily due to the liquidity issues experienced in global credit and capital markets, many auctions for auction rate securities have failed and the sellers of such securities have been unable to liquidate their securities. A seller must then wait until the next successful auction to attempt to sell its auction rate securities, unless there is a secondary market for the particular securities. As a result of a failed auction, however, the auction rate securities will generally pay interest to the holder at a maximum or default rate defined by the securities' governing documents.

During the years ended December 31, 2007 and 2006, we reported our marketable securities as short-term, classified as available-for-sale securities and recorded at cost, which approximated market value based on quoted market prices. At December 31, 2007, our entire \$6,025,000 portfolio of marketable securities was invested in AAA or Aaa rated auction rate securities. All of the auction rate securities in which we have invested are secured by pools of student loans, in excess of 90% of which are guaranteed under the Federal Family Education Loan Program ("FFELP"). We do not own, and have not invested in, any auction rate securities secured by mortgages or collateralized debt obligations.

Subsequent to December 31, 2007, all \$6,025,000 of our portfolio of marketable securities held at December 31, 2007 were sold through the Dutch auction process, with \$1,925,000 of the proceeds then invested in other select short-term marketable security investments and \$4,100,000 of the proceeds reinvested in auction rate securities. However, as described above, recent uncertainties in the global credit and capital markets have prevented sellers of auction rate securities, including us, from liquidating their holdings in auction rate securities. Since mid-February 2008, each of the remaining \$4,100,000 of auction rate securities that we held experienced, and has continued to experience, failed auctions. As a result of these failed auctions, we have been unable to liquidate our investment and do not expect to be able to access our funds that are invested in these auction rate securities until a future auction of these securities is successful or a secondary market develops for these particular securities. We included these \$4,100,000 of auction rate securities in long-term marketable securities in the accompanying consolidated balance sheet as of December 31, 2007 because we cannot predict when future auctions related to these securities will be successful or when we will be able to otherwise liquidate our investment.

We will continue to monitor the value of our auction rate securities each reporting period for a possible impairment if a decline in fair value occurs. On March 31, 2008, we received notification that the investment bank holding our auction rate securities will value these securities at approximately \$3,912,000, or 95.43% of par value, based upon an internal valuation model developed by the investment bank. This valuation model considered for each security such factors as liquidity, credit rating, underlying collateral, final maturity and applicable insurance when estimating value. Based upon this information, we may recognize a temporary reduction to our shareholders' equity in our financial statements as of and for the quarter ending March 31, 2008. We continue to earn interest at the maximum or default contractual rate on these auction rate securities as a result of their auction failures. We believe that our existing cash and marketable securities will provide sufficient funds to finance our operations for the next twelve months. We also believe that we would be able to obtain credit to provide additional working capital if our investments in these auction rate securities remained illiquid and we otherwise required additional liquidity.

Substantially all cash and cash equivalents and short-term marketable securities are presently held at one international securities brokerage firm, UBS. Accordingly, we are subject to credit risk if this brokerage firm is unable to repay the balance in the account or deliver our securities or if the brokerage firm should become bankrupt or otherwise insolvent. We invest in only select money market instruments, U.S. treasury investments, municipal and other governmental agency securities and corporate issuers.

Net cash flows of \$1,889,000 were provided during 2007 compared to \$1,364,000 that was used by operating activities during 2006. Cash provided during 2007 was primarily the result of the combination of the net loss for the period of \$10,434,000 offset by non-cash items and cash provided from changes in operating assets and liabilities. The non-cash items, which total \$7,926,000, include principally the goodwill impairment

charge and the write-off of PARSEC® System related assets, each as described in further detail above, as well as depreciation and amortization and deferred income taxes. Cash provided by changes in operating assets and liabilities of \$4,397,000 was partially the result of cash of \$1,718,000 received as a result of reductions in accounts receivable, primarily due to the effect of accounts receivable collections of previously outstanding accounts receivable balances based upon negotiated agreements with governmental regions in Italy acting on behalf of hospitals located within the region. Cash of \$1,986,000 provided by an increase in accounts payable and accrued expenses was principally the result of severance costs accrued for estimated costs associated with management and other personnel changes that occurred, or were being negotiated, during the fourth quarter of 2007. Included in this amount is the effect of a separation agreement and general release negotiated with Giorgio D'Urso upon his resignation, effective January 10, 2008, as our President and Chief Executive Officer and as a member of our Board of Directors. Pursuant to this agreement, we paid Mr. D'Urso a one-time lump-sum payment of \$495,000 and terminated the employment agreement that provided for Mr. D'Urso to serve as our President and Chief Executive Officer until February 24, 2010 at a minimum annual base salary of \$348,519. The remaining severance costs principally include estimated costs for the terminations of selected employees of Delta Biologicals, our Italian subsidiary, in 2007. Amounts actually paid in Italy will be subject to negotiations with the affected individuals and are subject to, and in some cases governed by, national collective and individual labor agreements existing in Italy. Cash used by operating activities during 2006 was partially the result of \$958,000 from the combination of the net loss for the period and non-cash items, which include principally depreciation and amortization, a write-off of inventory due to our third quarter 2006 write-off of assets relating to the PARSEC® System, a cumulative effect of a change in accounting principle in accordance with SFAS 123(R) and the effect of the provision for doubtful accounts receivable. Cash used by operating activities during 2006 was also the result of cash used for a net working capital increase, excluding the change in cash balance, of \$411,000. Cash provided from a decrease in inventories partially offset the net working capital increase caused principally by an increase in accounts receivable and a decrease in accounts payable and accrued expenses.

Net cash of \$65,000 was used by investing activities during 2007 compared to \$8,070,000 that was used by investing activities during 2006. The decrease in cash used by investing activities in 2007 compared to 2006 was primarily the result of our net investments in marketable securities. Additionally, cash flows used in investing activities increased during 2006, principally as a result of moving our Italian operations to a new facility and purchasing equipment which we expect to be necessary for the production of certain hepatitis products resulting from the license agreement we entered into in September 2004 with an Italian diagnostics company to obtain a perpetual, worldwide, royalty-free license of product technology used by the Italian diagnostics company. This licensed hepatitis product technology is existing technology, which the Italian diagnostics company had developed and successfully commercialized to manufacture hepatitis products sold by them and for which it had already received "CE Marking" approval from the European Union. Through the acquisition of this existing technology in its current form, we also expect to be able to derive revenue from the manufacture and sale of new hepatitis products. In exchange for the Italian diagnostics company's assistance in transferring the know-how of the manufacturing technology, we agreed to pay a total of 1,000,000 Euro in the form of four milestone payments upon the Italian diagnostics company's achievement of certain enumerated performance objectives related to the transfer of such existing technology. In March 2005, we paid the first of these milestone payments, in the amount of \$278,000. As a result of the satisfaction of the first performance objective and our corresponding payment of the first milestone payment, we determined that payment of the three remaining milestone payments was probable and, consequently, an accrued license payable for the remaining 800,000 Euro was recorded during the first quarter of 2005. In September 2006, the three remaining performance objectives, and the corresponding milestone payments, were slightly postponed. The delay had no effect on the carrying value of the product license. Following the completion of the second performance objective, the second milestone payment of \$524,000 was made in December 2006 and, following the completion of the third performance objective in October 2007, the third milestone payment of \$438,000 was made. The resulting accrued license payable in the accompanying balance sheet as of December 31, 2007 is \$147,000. We are now working with the Italian diagnostics company to achieve the remaining performance objective, which includes, among others, the condition for us to receive authorization for "CE Marking" in the European Union. The application for "CE Marking" was filed in January 2008, and we expect to pay the remaining license payable upon receipt of this

approval, which is expected in the second quarter of 2008. The remaining performance objective also includes requirements that training be provided to us. This training has been, and will continue to be, expensed as incurred and a corresponding amount will be recognized as a reduction to the product license recorded in the accompanying consolidated balance sheet. While we determined that our payment of the final milestone payment is probable and believe that capitalization as a recoverable asset is appropriate, there remains a risk that we will not be able to obtain product technology that would enable us to manufacture our own hepatitis products or, if we obtain such product technology, that we will not otherwise be able to manufacture our own hepatitis products. Additionally, as a result of our decision that we intend to change our strategic direction to focus on the development of the Mago<sup>®</sup> 4 instrument as a platform for marketing our kits and to place any further development of the PARSEC<sup>®</sup> System on hold indefinitely, the timeframe during which we expected to begin marketing these hepatitis test kits has been delayed. While we believe that we will be able to bring these hepatitis kits to market, if the progress of our efforts to begin marketing these kits is further adversely impacted, then we may be required to record an impairment charge with respect to all or a portion of the \$1,243,000 intangible hepatitis product license asset.

No cash was generated from financing activities during 2007 while net cash of \$34,000 was provided by financing activities during 2006. During 2006, cash was provided from the exercise of 26,333 options granted under our stock option plans.

Our product research and development expenditures are expected to be approximately \$1,700,000 during 2008. Actual expenditures will depend upon, among other things, the outcome of clinical testing of products under development, delays or changes in government required testing and approval procedures, technological and competitive developments, strategic marketing decisions and liquidity. There can be no assurance that these expenditures will result in the development of new products or product enhancements, that we will successfully complete products under development, that we will obtain regulatory approval or that any approved product will be produced in commercial quantities, at reasonable costs, and be successfully marketed. In addition, we estimate that cash of approximately \$500,000 will be required in 2008 to improve and expand our facilities, equipment and information systems. This estimate does not include, however, expenditures relating to our previously reported plans to continue our search to relocate to a new location for our corporate headquarters and the operations of Diamedix. There can be no assurance that we will be successful in our plans to expand or relocate our operations.

Our principal source of short term liquidity is existing cash and cash equivalents and short-term marketable securities, which we believe will be sufficient to meet our operating needs and anticipated capital expenditures over at least the next twelve months. Additionally, we may need to utilize cash to assist our Italian subsidiary, Delta Biologicals, in maintaining its compliance with capital requirements established by Italian law. For the long term, we intend to utilize principally existing cash and cash equivalents and marketable securities, as well as internally generated funds, which are anticipated to be derived primarily from the sale of existing diagnostic and instrumentation products and diagnostic and instrumentation products currently under development. To the extent that these sources of liquidity are insufficient, we may consider issuing debt or equity securities, incurring indebtedness or curtailing or reducing our operations.

We maintain allowances for doubtful accounts, particularly in Italy where payment cycles are longer than in the United States, for estimated losses resulting from the inability of our customers to make required or timely payments. Additionally, we periodically receive payments based upon negotiated agreements with governmental regions in Italy, acting on behalf of hospitals located in the region, in satisfaction of previously outstanding accounts receivable balances. We may anticipate collection of these amounts through a payment as described above, and, therefore, not provide an allowance for doubtful accounts for these amounts. If contemplated payments are not received, if existing agreements are not complied with or cancelled, or if we require additional allowances, then our operating results could be materially adversely affected during the period in which the determination to increase the allowance for doubtful accounts is or was made.

**Off-Balance Sheet Arrangements.** As of December 31, 2007, we had no off-balance sheet arrangements that are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

## **CRITICAL ACCOUNTING POLICIES**

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities. On an on-going basis, we evaluate our estimates, including those related to product returns, allowance for doubtful accounts, inventories, intangible assets, income, stock compensation and other tax accruals, warranty obligations, the realization of long-lived assets and contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our assumptions and estimates may, however, prove to have been incorrect and our actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies and the judgments and estimates we make concerning their application have significant impact on our consolidated financial statements.

### **REVENUE RECOGNITION**

A principal source of revenue is our "reagent rental" program in which customers make reagent kit purchase commitments with us that typically last for a period of three to five years. In exchange, we include a Mago® Plus instrument, which remains our property, and any required instrument service, which are paid for by the customer through these reagent kit purchases over the life of the commitment. We recognize revenue from the reagent kit sales when title passes, which is generally at the time of shipment. Should actual reagent kit or instrument failure rates significantly increase, our future operating results could be negatively impacted by increased warranty obligations and service delivery costs.

### **ALLOWANCE FOR DOUBTFUL ACCOUNTS**

We maintain allowances for doubtful accounts, particularly in Italy for the operations of our Italian subsidiary, for estimated losses resulting from the inability of our customers to make required payments. In many instances our receivables in Italy, while currently due and payable, take in excess of a year to collect. Additionally, we may receive payments based upon negotiated agreements with governmental regions in Italy, acting on behalf of hospitals located in the region, in satisfaction of previously outstanding accounts receivable balances. Consequently, we may consider the potential receipt of those types of payments in determining our allowance for doubtful accounts. If contemplated payments are not received when expected or at all, if negotiated agreements are not complied with in a timely manner or at all, or if the financial condition of our customers were to deteriorate resulting in an impairment of their ability to make payments, then our operating results could be materially adversely affected during the period in which the determination to increase the allowance for doubtful accounts is or was made. Our allowances for doubtful accounts were \$1,053,000 and \$1,093,000 at December 31, 2007 and 2006, respectively. Net provisions for losses on accounts receivable of \$14,000 and \$223,000 were recorded in 2007 and 2006, respectively.

### **INVENTORY**

We regularly review inventory quantities on hand, which include components for current or future versions of products and instrumentation. If necessary, we record a provision for excess and obsolete inventory based primarily on our estimates of component obsolescence, product demand and production requirements, as well as

based upon the status of a product within the regulatory approval process. We capitalize inventory costs associated with marketed products, and certain unapproved products prior to regulatory approval and product launch, based on management's judgment of probable future economic benefit which includes an assessment of probability of future commercial use and net realizable value. With respect to instrumentation products, we purchase instrument parts, and in some cases manufacture instrument components, in preparation for the commercial launch of the instrument in amounts sufficient to support forecasted initial market demand. We do not capitalize such inventory unless the product or instrument is considered to have a high probability of receiving regulatory approval. We may make this determination prior to our submission to the FDA of a 510(k) application or other required regulatory submission. In determining probability, if we are aware of any specific risks or contingencies that are likely to adversely impact the expected regulatory approval process, then we would not capitalize the related inventory but would instead expense it as incurred. Additionally, our estimates of future instrumentation and diagnostic kit product demand, or our judgment of probable future economic benefit, may prove to be inaccurate, in which case any resulting adjustments to the value of inventory would be recognized at the time of such determination and could adversely affect our operating results.

Inventory reserves were \$549,000 and \$421,000 as of December 31, 2007 and 2006, respectively. In addition to the write-offs related to the PARSEC® System in both 2007 and 2006, \$89,000 was charged to cost and expenses in 2007, while \$6,000 was charged to cost and expenses in 2006. Included in our inventory balance at December 31, 2007 was approximately \$70,000 in Mago® 4 instrumentation and instrument components in anticipation of our pending commercial product launch and \$200,000 in hepatitis inventory, which is currently pending regulatory approval based upon our January 2008 submission requesting "CE Marking" in the European Union. As a result of our decision that we intend to focus on the development of the Mago® 4 and put any further development of the PARSEC® System on hold indefinitely, we recorded an inventory write-down during the third quarter of 2007 of PARSEC® System inventory that was acquired in anticipation of the projected commercial launch. The inventory write-down, which totaled \$1,207,000, was composed of write-downs of raw materials, work-in-progress and finished goods inventory of \$618,000, \$515,000 and \$74,000, respectively.

## **GOODWILL AND OTHER INTANGIBLES**

Pursuant to SFAS No. 142, we analyze our goodwill at year-end for impairment issues and when triggering events of a possible impairment occur. In assessing the recoverability of our goodwill and other intangibles, we made assumptions regarding, among other things, estimated future cash flows, including current and projected levels of income, success of research and development projects, business trends, prospects and market conditions, to determine the fair value of the respected assets. If these or other estimates or their related assumptions change in the future, we may be required to record impairment charges for these assets not previously recorded. Any resulting impairment loss would be recorded as a charge against our earnings and could have a material adverse impact on our financial condition and results of operations.

During the third quarter of 2007 we determined, based principally upon the decline in our market capitalization to less than its June 30, 2007 book value for the preceding seven weeks prior to the end of the third quarter, as well as the decision we made during the third quarter of 2007 to change our strategic direction to place any further development of the PARSEC® System on hold indefinitely, that there was sufficient indication to require us to assess, in accordance with SFAS No. 142, whether any portion of our goodwill balance, which is recorded in both ImmunoVision and Delta Biologicals, was impaired. Based primarily upon our estimate of forecasted discounted cash flows for each of these subsidiaries and our market capitalization, we determined that the carrying amount of the goodwill at each of our Italian subsidiary, Delta Biologicals, and at ImmunoVision, one of our domestic subsidiaries, was in excess of its respective fair value. We concluded that all \$4,672,000 of the goodwill recorded at Delta Biologicals and \$1,180,000 of the \$2,050,000 of goodwill recorded at ImmunoVision was impaired. As a result, we recorded a noncash goodwill impairment charge to operations totaling \$5,852,000 during the third quarter of 2007. The continued decline in our market capitalization could require us to record additional impairment charges in future periods for the remaining goodwill for ImmunoVision.

The determination as to whether a write-down of goodwill is necessary involves significant judgment based upon our short-term and long-term projections for the Company. The assumptions supporting the estimated future cash flows of the reporting unit, including profit margins, long-term forecasts, discount rates and terminal growth rates, reflect our best estimates.

## STOCK-BASED COMPENSATION

Effective January 1, 2006, we adopted the fair value recognition provisions of SFAS 123(R) using the modified prospective transition method and therefore have not restated results for prior periods. Under this transition method, stock-based compensation expense for 2006 includes compensation expense for all stock-based compensation awards granted prior to, but not yet vested as of, January 1, 2006, based on the grant-date fair value estimate in accordance with the original provisions of SFAS 123. Stock-based compensation expense for all stock-based compensation awards granted after January 1, 2006 is based on the grant-date fair value estimate in accordance with the provisions of SFAS 123(R). We recognize these compensation costs on a straight-line basis over the requisite service period of the award, which is generally the option vesting term of either immediately, all at once after seven years or in equal annual amounts over a four year period.

Valuations are based on highly subjective assumptions about the future, including stock price volatility and exercise patterns. The fair value of share-based payment awards was estimated using the Black-Scholes option pricing model. Expected volatilities are based on the historical volatility of our stock. We use historical data to estimate option exercise and employee terminations. The expected term of options granted represents the period of time that options granted are expected to be outstanding. The risk-free rate for periods within the expected life of the option is based on the U.S. Treasury yield curve in effect at the time of the grant.

Prior to the adoption of SFAS No. 123(R), we accounted for stock-based compensation in accordance with Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees* ("APB 25").

## INCOME TAXES

We account for income taxes on our consolidated financial statements on a stand-alone basis as if we had filed our own income tax returns. However, the pre-merger IVAX Diagnostics reported its income taxes until the merger with b2bstores.com as part of a consolidated group. Therefore, all domestic net operating losses generated prior to the merger were utilized by IVAX. Since the merger, we have experienced net domestic losses from operations. Accounting principles generally accepted in the United States require that we record a valuation allowance against the deferred tax asset associated with these losses if it is "more likely than not" that we will not be able to utilize the net operating loss to offset future taxes. Due to the cumulative net losses from the operations of our domestic operations since the merger, we have provided a full valuation allowance against our domestic deferred tax assets. Additionally, we have no net foreign deferred tax asset, as a full valuation allowance was established in March 2005 as a result of losses generated by our Italian operation. Over time we may reach levels of profitability that could cause our management to conclude that it is more likely than not that we will realize all or a portion of our net operating loss carryforwards and other temporary differences. Upon reaching such a conclusion, and upon such time as we reverse the entire valuation allowance against the deferred tax asset, we would then provide for income taxes at a rate equal to our effective tax rate.

The critical accounting policies discussed above are not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by accounting principles generally accepted in the United States, with no need for management's judgment in their application. There are also areas in which management's judgment in selecting any available alternative would not produce a materially different result.

## RECENTLY ISSUED ACCOUNTING STANDARDS

In December 2007, the Financial Accounting Standards Board ("FASB") issued SFAS No. 141(R), *Business Combinations* ("SFAS 141(R)"). SFAS 141(R) will significantly change the accounting for business combinations in a number of areas including the treatment of contingent consideration, contingencies, acquisition costs, in-process research and development and restructuring costs. In addition, under SFAS 141(R), changes in deferred tax asset valuation allowances and acquired income tax uncertainties in a business combination after the measurement period will impact income tax expense. SFAS 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. Early application is not permitted. The effect of SFAS 141(R) on our consolidated financial statements will be dependent on the nature and terms of any business combinations that we consummate on or after January 1, 2009.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements* ("SFAS 160"). SFAS 160 amends Accounting Research Bulletin No. 51 to establish accounting and reporting standards for the noncontrolling (minority) interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements and establishes a single method of accounting for changes in a parent's ownership interest in a subsidiary that do not result in deconsolidation. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008. We do not expect the adoption of SFAS 160 to have a significant impact on our consolidated financial statements unless a future transaction results in a noncontrolling interest in a subsidiary.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* ("SFAS No. 159"). SFAS No. 159 permits a company to choose to measure many financial instruments and other items at fair value that are not currently required to be measured at fair value. The objective is to improve financial reporting by providing a company with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007 and, accordingly, we adopted the provisions of this Statement on January 1, 2008. We are currently evaluating the impact of the adoption of SFAS No. 159 on our consolidated financial statements. However, we do not expect the effect to be significant.

In June 2007, the FASB ratified Emerging Issues Task Force Issue 07-3, *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ("EITF 07-3"). EITF 07-3 provides guidance on the capitalization of non-refundable advance payments for goods and services to be used in future research and development activities until such goods have been delivered or the related services have been performed. As applicable to us, this pronouncement became effective for our fiscal year beginning on January 1, 2008. We do not expect the adoption of this pronouncement to have a material effect on our consolidated financial statements.

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109* ("FIN 48"). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in the enterprise's financial statements. This Interpretation 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 the tax return. We adopted the provisions of FIN 48 on January 1, 2007. As of the date of adoption, the 2003-2006 tax years remain subject to examination by major tax jurisdictions. As of December 31, 2007, the 2004-2006 tax years remain subject to examination by major tax jurisdictions.

As a result of the implementation of FIN 48, we recognized no material adjustments in the liability for unrecognized income tax benefits and, at the adoption date of January 1, 2007, we had no unrecognized tax benefits which would have affected our effective tax rate if recognized. At December 31, 2007, we also had no unrecognized tax benefits. If uncertain tax positions had been recorded, then we would recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2007, no accrued interest related to uncertain tax positions has been recorded.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ("SFAS No. 157"). SFAS No. 157 establishes a framework for measuring fair value and expands the disclosures on fair value measurements. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007 and, accordingly, we adopted the provisions of this Statement on January 1, 2008. We are currently evaluating the impact of the adoption of SFAS No. 157 on our consolidated financial statements. However, we do not expect the effect to be significant.

In September 2006, the Securities and Exchange Commission staff issued Staff Accounting Bulletin No. 108, *Considering the Effects of Prior Year Misstatement when Quantifying Misstatements in the Current Year Financial Statements* ("SAB 108"). SAB 108 was issued in order to eliminate the diversity in practice surrounding how public companies quantify financial statement misstatements.

Traditionally, there have been two widely-recognized methods for quantifying the effects of financial statement misstatements: the "roll-over" method and the "iron curtain" method. The roll-over method focuses primarily on the impact of a misstatement on the income statement, including the reversing effect of prior year misstatements, but its use can lead to the accumulation of misstatements in the balance sheet. The iron-curtain method, on the other hand, focuses primarily on the effect of correcting the period-end balance sheet with less emphasis on the reversing effects of prior year errors on the income statement. Prior to our application of the guidance in SAB 108, we used the roll-over method for quantifying financial statement misstatements.

In SAB 108, the Securities and Exchange Commission staff established an approach that requires quantification of financial statement misstatements based on the effects of the misstatements on each of the company's financial statements and the related financial statement disclosures. This model is commonly referred to as the "dual approach" because it requires quantification of errors under both the iron curtain and roll-over methods.

SAB 108 permits existing public companies to initially apply its provisions either by (i) restating prior financial statements as if the "dual approach" had always been applied or (ii) recording the cumulative effect of initially applying the "dual approach" as adjustments to the carrying values of assets and liabilities as of January 1, 2006 with an adjustment recorded to the opening balance of retained earnings. We elected to record the effects of applying SAB 108 using the cumulative effect transition method. The following table summarizes the effects (up to January 1, 2006) of applying the guidance of SAB 108:

	<u>Cumulative effect prior to January 1, 2004</u>	<u>2004</u>	<u>2005</u>	<u>Adjustment recorded as of January 1, 2006</u>
Deferred tax liabilities .....	\$381,613	\$63,492	\$63,492	\$508,597

We had previously determined that the adjustment was immaterial under our prior roll-over method policy and had not recognized a deferred tax liability with respect to domestic tax deductible goodwill.

During December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment* ("SFAS 123(R)"), which addresses the accounting for transactions in which an entity exchanges its equity instruments for goods or services. This Statement focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. It requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. We adopted the fair value recognition provisions of SFAS 123(R) using the modified prospective transition method (and therefore have not restated prior periods' results) effective January 1, 2006. The impact of adopting the modified prospective method of SFAS 123(R) during 2006 is discussed below in Note 2, *Summary of Significant Accounting Policies*, under the heading of *Stock-Based Compensation Plans*.

On January 1, 2006, we adopted SFAS No. 151, *Inventory Costs, an amendment of Accounting Research Bulletin No. 43*. The impact of adoption of this Statement was not significant.

## CURRENCY FLUCTUATIONS

For the years ended December 31, 2007 and 2006, approximately 31.3% and 33.1%, respectively, of our net revenues were generated in currencies other than the United States dollar. Fluctuations in the value of foreign currencies relative to the United States dollar affect our reported results of operations. If the United States dollar weakens relative to the foreign currency, then our earnings generated in the foreign currency will, in effect, increase when converted into United States dollars and vice versa. Exchange rate differences resulting from the strength or weakness of the United States dollar against the Euro resulted in increases of approximately \$520,000 in net revenues in 2007 compared to 2006. During the years ended December 31, 2007 and 2006, none of our subsidiaries were domiciled in a highly inflationary environment and the impact of inflation and changing prices on our net revenues and on our loss from continuing operations was not material.

During 2007, our subsidiary in Italy generated 31.3% of our net revenues. Conducting an international business inherently involves a number of difficulties, risks, and uncertainties, such as export and trade restrictions, inconsistent and changing regulatory requirements, tariffs and other trade barriers, cultural issues, labor and employment laws, longer payment cycles, problems in collecting accounts receivable, political instability, local economic downturns, seasonal reductions in business activity in Europe during the traditional summer vacation months, and potentially adverse tax consequences.

## INCOME TAXES

We recognized an income tax benefit of \$329,000 for the year ended December 31, 2007 compared to an income tax provision of \$153,000 for the year ended December 31, 2006. Through March 14, 2001, the pre-merger IVAX Diagnostics reported its domestic income taxes as part of a consolidated group with IVAX. All domestic taxable losses generated prior to that date were utilized by IVAX. Effective March 14, 2001, as a result of the merger between b2bstores.com and the pre-merger IVAX Diagnostics, we were no longer included in the consolidated income tax returns of IVAX.

Our income tax provision for the year ended December 31, 2007 was different from the amount computed on the income before income taxes at the statutory rate of 35% primarily due to the establishment of a full valuation allowance against the benefits of domestic and foreign losses. The 2007 current income tax was the result of Italian local income taxes based upon applicable statutory rates effective in Italy, while our deferred income tax was the result of domestic tax deductible goodwill, including the effect of a deferred tax benefit of \$460,200 recorded as a result of the third quarter 2007 impairment charge against the goodwill at ImmunoVision. Our income tax provision for the year ended December 31, 2006 was different from the amount computed on the income before income taxes at the statutory rate of 35% primarily due to the establishment of a full valuation allowance against the benefits of domestic and foreign losses. The 2006 current income tax was the result of Italian local income taxes based upon applicable statutory rates effective in Italy, while our deferred income tax was the result of domestic tax deductible goodwill.

As of December 31, 2007, we had no net domestic deferred tax asset, as domestic net operating losses generated prior to the merger between b2bstores.com and the pre-merger IVAX Diagnostics were utilized by IVAX and a full valuation allowance has been established against domestic deferred tax assets generated subsequent to March 14, 2001. As of December 31, 2007, we had net deferred tax liabilities relating to tax deductible goodwill of \$175,000, which was reduced by \$460,200 in the third quarter of 2007 as a result of the impairment charge against the goodwill at ImmunoVision. At December 31, 2007, we also had no net foreign deferred tax asset, as a result of the creation of a foreign valuation allowance in the first quarter of 2005 to fully reserve the remaining foreign deferred tax asset due to losses by our Italian operation. Subsequent revisions to the estimated net realizable value of the deferred tax asset or deferred tax liability could cause our provision for income taxes to vary significantly from period to period. Upon such time as we reverse the entire valuation allowance against the deferred tax asset, we would then provide for income taxes at a rate equal to our effective tax rate.

## **RISK OF PRODUCT LIABILITY CLAIMS**

Developing, manufacturing and marketing diagnostic test kits, reagents and instruments subject us to the risk of product liability claims. We believe that we continue to maintain an adequate amount of product liability insurance, but there can be no assurance that our insurance will cover all existing and future claims. There can be no assurance that claims arising under any pending or future product liability cases, whether or not covered by insurance, will not have a material adverse effect on our business, results of operations or financial condition. Our current products liability insurance is a "claims made" policy.

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

Not required.

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

**IVAX Diagnostics, Inc. and Subsidiaries  
Index to Consolidated Financial Statements**

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Consolidated Statements of Operations for the years ended December 31, 2007 and 2006 .....	43
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## **Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Shareholders of IVAX Diagnostics, Inc.:

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of IVAX Diagnostics, Inc. (the "Company") and its subsidiaries at December 31, 2007 and 2006, and the results of their operations and their cash flows for each of the two years in the period ended December, 31, 2007 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements 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, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

As discussed in Note 2 to the consolidated financial statements, the Company changed the manner in which it accounts for share based compensation in 2006.

/s/ PricewaterhouseCoopers LLP  
Philadelphia, PA  
March 31, 2008

**IVAX Diagnostics, Inc. and Subsidiaries**

**Consolidated Balance Sheets  
December 31, 2007 and 2006**

	<u>2007</u>	<u>2006</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents .....	\$ 3,900,564	\$ 1,995,730
Marketable securities .....	1,925,000	6,650,000
Accounts receivable, net of allowances for doubtful accounts of \$1,052,797 and \$1,093,070, respectively .....	6,287,654	7,489,272
Inventories, net .....	4,013,312	5,557,528
Other current assets .....	374,579	1,183,571
Total current assets .....	<u>16,501,109</u>	<u>22,876,101</u>
<b>PROPERTY, PLANT AND EQUIPMENT:</b>		
Land .....	352,957	352,957
Buildings and improvements .....	3,039,902	2,985,081
Machinery and equipment .....	2,534,084	2,825,404
Furniture and fixtures .....	1,887,369	1,788,170
	7,814,312	7,951,612
Less—Accumulated depreciation .....	<u>(5,969,020)</u>	<u>(5,650,032)</u>
	<u>1,845,292</u>	<u>2,301,580</u>
<b>OTHER ASSETS:</b>		
Marketable securities .....	4,100,000	—
Goodwill .....	870,290	6,722,725
Equipment on lease, net .....	163,113	386,762
Product license .....	1,242,936	1,255,936
Other .....	1,045,592	163,998
	7,421,931	8,529,421
Total assets .....	<u>\$ 25,768,332</u>	<u>\$ 33,707,102</u>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable .....	\$ 1,217,408	\$ 935,896
Accrued license payable .....	147,184	526,800
Accrued expenses .....	5,404,372	3,048,285
Total current liabilities .....	<u>6,768,964</u>	<u>4,510,981</u>
<b>OTHER LONG-TERM LIABILITIES:</b>		
Deferred tax liabilities .....	174,708	572,089
Other long-term liabilities .....	850,177	885,890
Total other long-term liabilities .....	<u>1,024,885</u>	<u>1,457,979</u>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>SHAREHOLDERS' EQUITY:</b>		
Common stock, par value \$0.01, authorized 50,000,000 shares, issued and outstanding 27,649,887 in 2007 and 2006 .....	276,498	276,498
Additional paid-in capital .....	40,910,677	40,781,825
Accumulated deficit .....	(23,209,941)	(12,776,202)
Accumulated other comprehensive loss .....	(2,751)	(543,979)
Total shareholders' equity .....	<u>17,974,483</u>	<u>27,738,142</u>
Total liabilities and shareholders' equity .....	<u>\$ 25,768,332</u>	<u>\$ 33,707,102</u>

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

**IVAX Diagnostics, Inc. and Subsidiaries**  
**Consolidated Statements of Operations**  
**For the Years Ended December 31, 2007 and 2006**

	<u>2007</u>	<u>2006</u>
NET REVENUE .....	\$ 19,975,870	\$19,523,471
COST OF SALES .....	<u>8,399,399</u>	<u>8,457,855</u>
Gross profit .....	<u>11,576,471</u>	<u>11,065,616</u>
OPERATING EXPENSES:		
Selling .....	5,485,532	5,883,610
General and administrative .....	7,730,164	5,652,392
Research and development .....	2,152,114	1,894,971
Write-off of PARSEC® related assets .....	1,673,824	509,000
Impairment of goodwill .....	<u>5,852,435</u>	<u>—</u>
Total operating expenses .....	<u>22,894,069</u>	<u>13,939,973</u>
Loss from operations .....	<u>(11,317,598)</u>	<u>(2,874,357)</u>
OTHER INCOME, NET:		
Interest income .....	435,575	463,882
Other income (expense), net .....	<u>119,515</u>	<u>(44,380)</u>
Total other income, net .....	<u>555,090</u>	<u>419,502</u>
Loss before income taxes .....	<u>(10,762,508)</u>	<u>(2,454,855)</u>
INCOME TAX PROVISION (BENEFIT) .....	<u>(328,769)</u>	<u>153,379</u>
LOSS BEFORE CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE .....	<u>(10,433,739)</u>	<u>(2,608,234)</u>
CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE .....	<u>—</u>	<u>(201,000)</u>
Net loss .....	<u><u>\$(10,433,739)</u></u>	<u><u>\$(2,809,234)</u></u>
Loss per share, before cumulative effect of change in accounting principle		
Basic and diluted .....	<u>\$ (0.38)</u>	<u>\$ (0.09)</u>
Cumulative effect of change in accounting principle, per share		
Basic and diluted .....	<u>\$ —</u>	<u>\$ (0.01)</u>
Loss per share		
Basic and diluted .....	<u>\$ (0.38)</u>	<u>\$ (0.10)</u>
WEIGHTED AVERAGE SHARES OUTSTANDING:		
Basic .....	<u>27,649,887</u>	<u>27,639,221</u>
Diluted .....	<u>27,649,887</u>	<u>27,639,221</u>

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

**IVAX Diagnostics, Inc. and Subsidiaries**  
**Consolidated Statements of Shareholders' Equity**  
**For the Years Ended December 31, 2007 and 2006**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
	Shares	Amount				
BALANCE, December 31, 2005 .....	27,623,554	276,235	\$40,548,950	\$ (9,458,371)	\$(1,177,250)	\$ 30,189,564
Cumulative effect of the adoption of SAB 108 .....	—	—	—	(508,597)	—	(508,597)
Comprehensive loss:						
Net loss .....	—	—	—	(2,809,234)	—	(2,809,234)
Translation adjustment .....	—	—	—	—	633,271	633,271
Comprehensive loss .....						(2,175,963)
Exercise of stock options .....	26,333	263	34,210	—	—	34,473
Stock compensation .....	—	—	198,665	—	—	198,665
BALANCE, December 31, 2006 .....	27,649,887	\$276,498	\$40,781,825	\$(12,776,202)	\$ (543,979)	\$ 27,738,142
Comprehensive loss:						
Net loss .....	—	—	—	(10,433,739)	—	(10,433,739)
Translation adjustment .....	—	—	—	—	541,228	541,228
Comprehensive loss .....						(9,892,511)
Stock compensation .....	—	—	128,852	—	—	128,852
BALANCE, December 31, 2007 .....	<u>27,649,887</u>	<u>\$276,498</u>	<u>\$40,910,677</u>	<u>\$(23,209,941)</u>	<u>\$ (2,751)</u>	<u>\$ 17,974,483</u>

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

**IVAX Diagnostics, Inc. and Subsidiaries**  
**Consolidated Statements of Cash Flows**  
**For the Years Ended December 31, 2007 and 2006**

	2007	2006
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss .....	\$(10,433,739)	\$(2,809,234)
Adjustments to reconcile net loss to net cash provided by operating activities-		
Depreciation and amortization .....	677,074	799,040
Provision for doubtful accounts receivable .....	14,016	222,652
Non-cash compensation, including fair value adjustments of liability awards .....	105,852	20,664
Deferred income tax provision (benefit) .....	(397,381)	63,492
Cumulative effect of a change in accounting principle .....	—	201,000
Impairment of goodwill .....	5,852,435	—
Write-off of certain PARSEC instrumentation assets including prior period depreciation in 2006 .....	1,673,824	509,000
Loss on disposal of assets .....	—	35,402
Changes in operating assets and liabilities:		
Accounts receivable .....	1,718,003	(485,361)
Inventories .....	489,414	238,192
Other current assets .....	(26,187)	86,587
Other assets .....	1,544	(97,665)
Accounts payable and accrued expenses .....	1,986,473	(249,998)
Other long-term liabilities .....	227,686	102,356
Net cash provided by (used in) operating activities .....	1,889,014	(1,363,873)
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Capital expenditures .....	(175,926)	(881,828)
Acquisition of equipment on lease .....	(76,289)	(145,244)
Acquisition of product license .....	(438,000)	(523,840)
Purchases of marketable securities .....	(575,000)	(8,750,000)
Proceeds from sales of marketable securities .....	1,200,000	2,230,918
Net cash used in investing activities .....	(65,215)	(8,069,994)
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from stock option exercises .....	—	34,473
Net cash provided by financing activities .....	—	34,473
<b>EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS</b>		
EQUIVALENTS .....	81,035	(84,444)
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b> .....	1,904,834	(9,483,838)
<b>CASH AND CASH EQUIVALENTS, beginning of year</b> .....	1,995,730	11,479,568
<b>CASH AND CASH EQUIVALENTS, end of year</b> .....	\$ 3,900,564	\$ 1,995,730
<b>SUPPLEMENTAL DISCLOSURES:</b>		
Income taxes paid .....	\$ 97,141	\$ 90,357

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

**IVAX Diagnostics, Inc. and Subsidiaries**  
**Notes to Consolidated Financial Statements**

**1 ORGANIZATION AND OPERATIONS**

IVAX Diagnostics, Inc. ("IVAX Diagnostics" or the "Company") is a Delaware corporation and, through its subsidiaries, is engaged in developing, manufacturing and marketing diagnostic test kits, reagents and instruments for use in hospitals, reference laboratories, clinical laboratories, research laboratories, doctors' offices and other commercial companies. The Company's products and instrumentation are sold primarily to customers in the United States and Italy.

On July 25, 2005, IVAX Corporation ("IVAX"), which then owned approximately 72.3% of the outstanding shares of the Company's common stock, entered into a definitive agreement and plan of merger with Teva Pharmaceutical Industries Limited ("Teva"), providing for IVAX to be merged into a wholly-owned subsidiary of Teva. On January 26, 2006, the merger was consummated and IVAX became a wholly-owned subsidiary of Teva for an aggregate purchase price of approximately \$3.8 billion in cash and 123 million Teva ADRs. The transaction was reported to be valued, for accounting purposes, at \$7.9 billion, based on the value of the Teva ADRs during the five trading day period commencing two trading days before the date of the definitive agreement and plan of merger. As a result of the merger, Teva now, indirectly through its IVAX subsidiary, owns approximately 72.3% of the outstanding shares of the Company's common stock.

**2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

**Principles of Consolidation**

The accompanying consolidated financial statements include the accounts of the Company and its subsidiaries. All significant intercompany balances and transactions have been eliminated in consolidation.

*Use of Estimates*

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities, at the date of and for the period of the financial statements. The Company's actual results in subsequent periods may differ from the estimates and judgments used in the preparation of the accompanying consolidated financial statements. Significant estimates include the allowance for doubtful accounts, inventories, intangible assets, income and other tax accruals, severance accruals, warranty obligations, stock based compensation, the realization of long-lived assets and contingencies and litigation.

*Recently Issued Accounting Standards*

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations* ("SFAS 141(R)"). SFAS 141(R) will significantly change the accounting for business combinations in a number of areas including the treatment of contingent consideration, contingencies, acquisition costs, in-process research and development and restructuring costs. In addition, under SFAS 141(R), changes in deferred tax asset valuation allowances and acquired income tax uncertainties in a business combination after the measurement period will impact income tax expense. SFAS 141(R) applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. Early application is not permitted. The effect of SFAS 141(R) on the Company's consolidated financial statements will be dependent on the nature and terms of any business combinations consummated by the Company on or after January 1, 2009.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements* ("SFAS 160"). SFAS 160 amends Accounting Research Bulletin No. 51 to establish accounting and

reporting standards for the noncontrolling (minority) interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements and establishes a single method of accounting for changes in a parent's ownership interest in a subsidiary that do not result in deconsolidation. SFAS 160 is effective for fiscal years beginning on or after December 15, 2008. The Company does not expect the adoption of SFAS 160 to have a significant impact on its consolidated financial statements unless a future transaction results in a noncontrolling interest in a subsidiary.

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* ("SFAS No. 159"). SFAS No. 159 permits a company to choose to measure many financial instruments and other items at fair value that are not currently required to be measured at fair value. The objective is to improve financial reporting by providing a company with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007 and, accordingly, the Company adopted the provisions of this Statement on January 1, 2008. The Company is currently evaluating the impact of the adoption of SFAS No. 159 on its consolidated financial statements. However, it does not expect the effect to be significant.

In June 2007, the FASB ratified Emerging Issues Task Force Issue 07-3, *Accounting for Advance Payments for Goods or Services to Be Used in Future Research and Development Activities* ("EITF 07-3"). EITF 07-3 provides guidance on the capitalization of non-refundable advance payments for goods and services to be used in future research and development activities until such goods have been delivered or the related services have been performed. As applicable to the Company, this pronouncement became effective for the fiscal year beginning on January 1, 2008. The Company does not expect the adoption of this pronouncement to have a material effect on its consolidated financial statements.

In July 2006, the FASB issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109* ("FIN 48"). FIN 48 clarifies the accounting for uncertainty in income taxes recognized in the enterprise's financial statements. This Interpretation 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 the tax return. The Company adopted the provisions of FIN 48 on January 1, 2007. As of the date of adoption, the 2003-2006 tax years remain subject to examination by major tax jurisdictions. As of December 31, 2007, the 2004-2006 tax years remain subject to examination by major tax jurisdictions.

As a result of the implementation of FIN 48, the Company recognized no material adjustments in the liability for unrecognized income tax benefits and, at the adoption date of January 1, 2007, had no unrecognized tax benefits which would have affected its effective tax rate if recognized. At December 31, 2007, the Company also had no unrecognized tax benefits. If uncertain tax positions had been recorded, then the Company would recognize interest and penalties related to uncertain tax positions in income tax expense. As of December 31, 2007, no accrued interest related to uncertain tax positions has been recorded.

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Traditionally, there have been two widely-recognized methods for quantifying the effects of financial statement misstatements: the "roll-over" method and the "iron curtain" method. The roll-over method focuses primarily on the impact of a misstatement on the income statement, including the reversing effect of prior year

misstatements, but its use can lead to the accumulation of misstatements in the balance sheet. The iron-curtain method, on the other hand, focuses primarily on the effect of correcting the period-end balance sheet with less emphasis on the reversing effects of prior year errors on the income statement. Prior to the Company's application of the guidance in SAB 108, the Company used the roll-over method for quantifying financial statement misstatements.

In SAB 108, the Securities and Exchange Commission staff established an approach that requires quantification of financial statement misstatements based on the effects of the misstatements on each of the company's financial statements and the related financial statement disclosures. This model is commonly referred to as the "dual approach" because it requires quantification of errors under both the iron curtain and roll-over methods.

SAB 108 permits existing public companies to initially apply its provisions either by (i) restating prior financial statements as if the "dual approach" had always been applied or (ii) recording the cumulative effect of initially applying the "dual approach" as adjustments to the carrying values of assets and liabilities as of January 1, 2006 with an adjustment recorded to the opening balance of retained earnings. The Company elected to record the effects of applying SAB 108 using the cumulative effect transition method. The following table summarizes the effects (up to January 1, 2006) of applying the guidance of SAB 108:

	Cumulative effect prior to January 1, 2004	2004	2005	Adjustment recorded as of January 1, 2006
Deferred tax liabilities .....	\$381,613	\$63,492	\$63,492	\$508,597

The Company, which determined that the adjustment was immaterial under the Company's prior roll-over method policy, had previously not recognized a deferred tax liability with respect to domestic tax deductible goodwill.

During December 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment* ("SFAS 123(R)"), which addresses the accounting for transactions in which an entity exchanges its equity instruments for goods or services. This Statement focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. It requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. The Company adopted the fair value recognition provisions of SFAS 123(R) using the modified prospective transition method (and therefore has not restated prior periods' results) effective January 1, 2006. The impact of adopting the modified prospective method of SFAS 123(R) during 2006 is discussed below in this Note 2, *Summary of Significant Accounting Policies*, under the heading of *Stock-Based Compensation Plans*.

On January 1, 2006, the Company adopted SFAS No. 151, *Inventory Costs, an amendment of Accounting Research Bulletin No. 43*. The impact of adoption of this Statement was not significant.

#### *Cash and Cash Equivalents*

The Company considers all investments with a maturity of three months or less as of the date of purchase to be cash equivalents.

#### *Marketable Debt Securities*

The Company invests in only select money market instruments, U.S. treasury investments, municipal and other governmental agency securities and corporate issuers. In the years ended December 31, 2007 and 2006, consistent with the Company's historical investment policies, available cash was typically invested in auction rate securities with long-term maturities (generally between 20 and 30 years), the interest rates of which are reset periodically (typically every 28 or 35 days) through a competitive bidding process often referred to as a "Dutch auction." Despite the underlying long-term maturity of these securities, such securities were typically priced and subsequently traded as short-term investments because of their interest rate reset feature. Realized gains and

losses from sales of marketable securities are based on the specific identification method. For the years ended December 31, 2007 and 2006, realized gains and losses were not material, as recorded book value approximated fair value. The Company received proceeds of \$1,200,000 and \$2,230,918 for the sale of marketable securities, and used \$575,000 and \$8,750,000 for the purchase of marketable securities in 2007 and 2006, respectively.

The Dutch auction process has historically provided a liquid market for auction rate securities, as this mechanism generally allows existing investors to rollover their holdings and continue to own their respective securities at then existing market interest rates or to liquidate their holdings by selling their securities at par value. Recently, however, primarily due to the liquidity issues experienced in global credit and capital markets, many auctions for auction rate securities have failed and the sellers of such securities have been unable to liquidate their securities. A seller must then wait until the next successful auction to attempt to sell its auction rate securities, unless there is a secondary market for the particular securities. As a result of a failed auction, however, the auction rate securities will generally pay interest to the holder at a maximum or default rate defined by the securities' governing documents.

At December 31, 2007, the Company's entire \$6,025,000 portfolio of marketable securities was invested in AAA or Aaa rated auction rate securities. All of the auction rate securities in which we have invested are secured by pools of student loans, in excess of 90% of which are guaranteed under the Federal Family Education Loan Program ("FFELP"), and each had a credit rating of AAA or Aaa when purchased. The Company does not own, and has not invested in, any auction rate securities secured by mortgages or collateralized debt obligations. Subsequent to December 31, 2007, all \$6,025,000 of the Company's portfolio of marketable securities held at December 31, 2007 were sold through the Dutch auction process, with \$1,925,000 of the proceeds then invested in other select short-term marketable security investments and \$4,100,000 of the proceeds reinvested in auction rate securities. However, as described above, recent uncertainties in the global credit and capital markets have prevented sellers of auction rate securities, including the Company, from liquidating their holdings in auction rate securities. Since mid-February 2008, as described in Note 16, *Subsequent Event*, each of the remaining \$4,100,000 of auction rate securities that the Company held experienced, and has continued to experience, failed auctions. As a result of these failed auctions, the Company has been unable to liquidate its investment and does not expect to be able to access its funds that are invested in these auction rate securities until a future auction of these securities is successful or a secondary market develops for these particular securities. The Company included these \$4,100,000 of auction rate securities in long-term marketable securities in the accompanying consolidated balance sheet as of December 31, 2007 because it cannot predict when future auctions related to these securities will be successful or when the Company will be able to otherwise liquidate its investment. The Company believes that these auction rate securities are not impaired at December 31, 2007 because all of the securities held were successful at auction in January 2008. The Company will, however, continue to monitor the value of its auction rate securities each reporting period for a possible impairment if a decline in fair value occurs. The Company continues to earn interest at the maximum or default contractual rate on these auction rate securities as a result of their auction failures.

#### *Accounts Receivable and Allowance for Doubtful Accounts*

The Company grants credit without collateral to its customers based on the Company's evaluation of a particular customer's credit worthiness. In addition, allowances for doubtful accounts are maintained, particularly in Italy where payment cycles are longer than in the United States, for potential credit losses based on the age of the accounts receivable and the results of the Company's periodic credit evaluations of its customers' financial condition. Accounts receivable are written off after collection efforts have been followed in accordance with the Company's policies. Accounts written off as uncollectible are deducted from the allowance for doubtful accounts, while subsequent recoveries are netted against provision for doubtful accounts expense. The Company does not charge interest on accounts receivable.

The Company periodically receives, and may in the future receive, payments based upon negotiated agreements with governmental regions in Italy, acting on behalf of hospitals located in the region, in satisfaction of previously outstanding accounts receivable balances. As a result, the Company may anticipate the potential

receipt of these payments and, therefore, not provide an allowance for doubtful accounts for these amounts. If contemplated payments are not received when expected or at all, or if negotiated agreements are not complied with in a timely manner or cancelled, then the Company may provide additional allowances for doubtful accounts.

The allowance for doubtful accounts was \$1,052,797 and \$1,093,070 at December 31, 2007 and 2006, respectively, and activity for the years then ended was as follows:

	<u>2007</u>	<u>2006</u>
January 1 balance .....	\$1,093,070	\$ 973,855
Provision .....	14,016	222,652
Write-offs .....	(132,928)	(184,005)
Effects of changes in foreign exchange rates .....	78,639	80,568
Balance at December 31 .....	<u>\$1,052,797</u>	<u>\$1,093,070</u>

### *Inventories*

Inventories are stated at the lower of cost (first-in, first-out) or market. Components of inventory cost include materials, labor and manufacturing overhead. In evaluating whether inventory is stated at the lower of cost or market, management considers such factors as the amount of inventory on hand, estimated time required to sell such inventory, remaining shelf life and current market conditions. Inventory costs associated with marketed products are capitalized, as are certain unapproved products prior to regulatory approval and product launch, based on management's judgment of probable future economic benefit which includes an assessment of probability of future commercial use and net realizable value. With respect to instrumentation products, the Company purchases instrument parts, and in some cases manufactures instrument components, in preparation for the commercial launch of the instrument in amounts sufficient to support forecasted initial market demand. Inventory is not capitalized unless the product or instrument is considered to have a high probability of receiving regulatory approval. The Company may make this determination prior to its submission to the FDA of a 510(k) application or other required regulatory submission. In determining probability, if the Company is aware of any specific risks or contingencies that are likely to adversely impact the expected regulatory approval process, then it would not capitalize the related inventory but would instead expense it as incurred. Reserves are provided as appropriate to reduce excess or obsolete inventories to the lower of cost or market. Inventories consist of the following:

	<u>December 31,</u>	
	<u>2007</u>	<u>2006</u>
Raw materials .....	\$ 718,909	\$1,190,933
Work-in-process .....	862,857	1,570,680
Finished goods .....	2,431,546	2,795,915
Total .....	<u>\$4,013,312</u>	<u>\$5,557,528</u>

In accordance with our inventory accounting policy, total inventories at December 31, 2007 include components for current or future versions of products and instrumentation, including approximately \$70,000 in Mago<sup>®</sup> 4 instrumentation and instrument components in anticipation of the future commercial product launch and \$200,000 in hepatitis inventory, which is currently pending regulatory approval based upon the Company's January 2008 submission requesting "CE Marking" in the European Union. Mago<sup>®</sup> 4 instrumentation and instrument components and hepatitis inventory at December 31, 2006 were not significant. As discussed below in Note 3, *Write-off of PARSEC<sup>®</sup> Assets*, the Company's decision that it intends to focus on the development of the Mago<sup>®</sup> 4 and put any further development of the PARSEC<sup>®</sup> System on hold indefinitely resulted in an inventory write-down during the third quarter of 2007 of PARSEC<sup>®</sup> System inventory that was acquired in anticipation of the projected commercial launch. The inventory write-down, which totaled \$1,206,655, was composed of raw materials, work-in-progress and finished goods inventory of \$617,994, \$514,692 and \$73,969, respectively.

### Property, Plant and Equipment

Property, plant and equipment are carried at cost, less accumulated depreciation. Depreciation is computed on the straight-line basis over the estimated useful lives of the assets as follows:

	<u>Years</u>
Buildings and improvements .....	5-20
Machinery and equipment .....	3-10
Furniture and fixtures .....	3-10

Costs of major additions and improvements are capitalized and expenditures for maintenance and repairs which do not extend the life of the assets are expensed. Upon sale or disposition of property, plant and equipment, the cost and related accumulated depreciation is eliminated from the accounts and any resulting gain or loss is credited or charged to operations.

Depreciation expense related to property, plant and equipment was \$389,594 and \$447,813 for the years ended December 31, 2007 and 2006, respectively.

### Equipment on Lease, Net

The cost of the Company's owned instruments, which are placed under reagent rental programs at customer facilities for testing and usage of the Company's products (see this Note 2, *Summary of Significant Accounting Policies*, under the heading of *Revenue Recognition*), less accumulated amortization, consists of the following:

	<u>December 31,</u>	
	<u>2007</u>	<u>2006</u>
Equipment on lease, at cost .....	\$6,358,894	\$6,044,746
Less—Accumulated amortization .....	6,195,781	5,657,984
	<u>\$ 163,113</u>	<u>\$ 386,762</u>

Equipment on lease is amortized over three years. Amortization expense related to equipment on lease was \$274,480 and \$351,227 for the years ended December 31, 2007 and 2006, respectively.

### Long Lived Assets Including Goodwill

Goodwill consists of the following:

	<u>December 31,</u>	
	<u>2007</u>	<u>2006</u>
Goodwill .....	\$1,262,033	\$9,139,755
Less—Accumulated amortization .....	391,743	2,417,030
	<u>\$ 870,290</u>	<u>\$6,722,725</u>

As discussed in Note 4, *Impairment of Long Lived Assets including Goodwill*, in accordance with SFAS 142, *Goodwill and Other Intangible Assets*, the Company tests goodwill for possible impairment on an annual basis and at any other time events occur or circumstances indicate that the carrying amount of goodwill may be impaired. During the third quarter of 2007, based principally upon the decline in the Company's market capitalization to less than its June 30, 2007 book value for the preceding seven weeks prior to the end of the third quarter of 2007, as well as the decision the Company made during the third quarter of 2007 to change its strategic direction to place any further development of the PARSEC® System on hold indefinitely, the Company

determined that there was sufficient indication to require it to assess whether any portion of its recorded goodwill balance was impaired. This assessment resulted in the Company recording a noncash goodwill impairment charge to operations totaling \$5,852,435 during the third quarter of 2007.

Additionally, as discussed below in Note 3, *Write-off of PARSEC® Assets*, certain other long-lived assets, consisting of assets related to the PARSEC® System included in property, plant and equipment and equipment on lease, were assessed for impairment in accordance with SFAS No. 144 prior to the performance of the SFAS No. 142 analysis and were also determined to be impaired during the third quarter of 2007. Assets related to the PARSEC® System included in property and equipment were written down in the amount of \$337,912 and assets related to the PARSEC® System included in equipment on lease were written down by \$48,579 during the third quarter of 2007. These charges were included in operating expenses in the accompanying statements of operations for the year ended December 31, 2007.

#### *Foreign Currencies*

The Company's operations include operations that are located in Italy. Assets and liabilities as stated in the local reporting and functional currency are translated at the rate of exchange prevailing at the balance sheet date. The gains or losses that result from this process are shown in the "Accumulated other comprehensive loss" caption in the Shareholders' Equity section of the accompanying consolidated balance sheets. Amounts in the consolidated statements of operations are translated at the average exchange rates for the period.

The Company is exposed to the risk of currency fluctuation, as a significant portion of its operations are in Italy. The Company does not use financial derivatives.

#### *Financial Instruments*

The carrying amounts of cash and cash equivalents, marketable securities, accounts receivable, and accounts payable approximate fair value due to the short-term maturity of the instruments. The Company does not speculate in the foreign exchange market.

#### *Revenue Recognition*

Revenue and the related cost of sales on sales of test kits and instruments are recognized when risk of loss and title passes, which is generally at the time of shipment. Net revenue is comprised of gross revenue less provisions for expected product returns, allowances and discounts and warranty claims. Provisions and discounts for the years ended December 31, 2007 and 2006 were not significant.

The Company also owns instruments that it places, under "reagent rental" programs common to the industry, for periods of time at customer facilities for usage with the Company's products ("equipment on lease"). The instrument system, which remains the property of the Company, is utilized by customers to expedite the performance of certain tests and its use, including any required instrument service, is paid for by the customer through reagent kit purchases over the agreed upon contract period, typically three to five years. Upon completion of the contract period, the instrument is returned to the Company.

Provisions for estimated warranty claims are established by the Company concurrently with the recognition of revenue. Provisions are established in accordance with United States generally accepted accounting principles based upon consideration of a variety of factors, including actual experience for products during the past several years by product type, the market for the product and projected economic conditions. Actual product returns, allowances and discounts and warranty claims incurred are, however, dependent upon future events. The Company continually monitors the factors that influence product returns, allowances and discounts and warranty claims and makes adjustments to these provisions when management believes that actual amounts may differ from established reserves.

Shipping and handling fees billed to customers are recognized in net revenue. Shipping and handling costs are included in cost of sales.

*Research and Development Costs*

Research and development costs related to future products are expensed as incurred.

*Stock-Based Compensation Plans*

Effective January 1, 2006, the Company adopted the fair value recognition provisions of SFAS 123(R) using the modified prospective transition method. Under this transition method, stock-based compensation expense for the year ended December 31, 2006 included compensation expense for all stock-based compensation awards granted prior to, but not yet vested as of January 1, 2006, based on the grant-date fair value estimate in accordance with the original provisions of SFAS No. 123. Stock-based compensation expense for all share-based payment awards granted after January 1, 2006 is based on the grant-date fair value estimate in accordance with the provisions of SFAS 123(R). The Company estimates forfeitures for employee stock options and recognizes the compensation costs for only those options expected to vest. Forfeiture rates are determined for two groups, for directors and senior management and for all other employees, based upon historical experience. Estimated forfeitures are adjusted to actual forfeiture experience as needed. The cumulative effect of the change in forfeiture rates was immaterial.

The adoption of SFAS 123(R) on January 1, 2006 resulted in a cumulative effect adjustment of \$201,000, which reflects the change in classification of certain options granted in March 2001 from an equity award grant to a liability award in accordance with SFAS 123(R). The award has an acceleration provision, pursuant to which the holder of the award can accelerate the vesting by purchasing stock of the Company. Under SFAS 123(R), this award requires reclassification as a liability. Given the decline in the Company's share price, the resulting liability was reduced to \$23,000 at December 31, 2006 and \$0 at December 31, 2007. The resulting fair value adjustments of \$178,000 during the year ended December 31, 2006 and \$23,000 during the year ended December 31, 2007 have been reported as reductions of general and administrative expenses in the accompanying statements of operations.

At December 31, 2007, the Company had two stock-based employee compensation plans as described below. As a result of adopting SFAS 123(R) on January 1, 2006, the Company recorded total compensation expense, including the effect of the reduction in the Company's stock option compensation liability, of \$105,852 and \$20,664 for the years ended December 31, 2007 and December 31, 2006, respectively.

*Comprehensive Loss*

The components of the Company's comprehensive loss are as follows:

	<u>Year Ended December 31,</u>	
	<u>2007</u>	<u>2006</u>
Net loss .....	\$(10,433,739)	\$(2,809,234)
Foreign currency translation adjustment .....	541,228	633,271
Comprehensive loss .....	<u>\$ (9,892,511)</u>	<u>\$(2,175,963)</u>

*Loss per Share*

Loss per share is computed by dividing net loss by the weighted average number of shares of common stock outstanding during the year. All outstanding stock options and warrants are considered potential common stock. The dilutive effect, if any, of stock options and warrants is calculated using the treasury stock method.

A reconciliation of the denominator of the basic and diluted loss per share computation for the years ended December 31, 2007 and 2006 is as follows:

	Year Ended December 31,	
	2007	2006
Basic weighted average shares outstanding .....	27,649,887	27,639,221
Effect of diluted securities—		
Stock options and warrants .....	—	—
Diluted weighted average shares outstanding .....	<u>27,649,887</u>	<u>27,639,221</u>
Not included in the calculation of diluted loss per share because their impact is antidilutive:		
Stock options and warrants outstanding .....	<u>784,949</u>	<u>819,549</u>

### 3 WRITE-OFF OF PARSEC® ASSETS

The Company recorded a \$1,673,824 write-off of net assets relating to the PARSEC® System during the third quarter of 2007 as a result of the Company's continuing evaluation of the status of the development of its PARSEC® System and the decision it made during the third quarter of 2007 to change its strategic direction to focus on the development of its new Mago® 4 instrument as a platform for marketing the Company's kits and to place any further development of the PARSEC® System on hold indefinitely. As discussed in Note 2, *Summary of Significant Accounting Policies*, under the heading of *Inventories*, raw material, work-in-process and finished goods inventories comprised \$1,206,655 of this write-off. Additionally, the remaining portion of this write-off was composed of property, plant and equipment with a net book value of \$337,912, equipment on lease with a net book value of \$48,579 and other current assets of \$80,678. These charges were included in operating expenses in the accompanying statements of operations for the year ended December 31, 2007.

During the third quarter of 2006, the Company recorded in operating expenses a \$509,000 write-off of assets relating to the PARSEC® System when the Company determined, as part of its continuing assessment of PARSEC® System assets, that certain of these assets were not compatible with future instrument versions. Included in this total adjustment was \$278,000 in assets associated with PARSEC® System development and \$77,000 in inventory. While performing the analysis that resulted in this determination, the Company became aware of, and included in this adjustment, errors in prior periods totaling \$154,000, primarily related to still usable fixed assets relating to the PARSEC® System that had not been properly depreciated. Had these errors been recorded in the proper prior periods, for the years ended December 31, 2003, 2004 and 2005 and 2006, both income from operations and income before income taxes would have been lower by \$51,000, \$41,000, \$42,000 and \$20,000, respectively. The Company concluded that this adjustment did not have a material effect on the 2006 or previously filed financial statements.

### 4 IMPAIRMENT OF LONG-LIVED ASSETS INCLUDING GOODWILL

Effective January 1, 2002, the Company adopted SFAS No. 142, *Goodwill and Other Intangible Assets* ("SFAS No. 142"), which was issued by the FASB in July 2001. Under this standard, the Company ceased amortizing goodwill effective January 1, 2002.

SFAS No. 142 makes use of the concept of reporting units. All acquisitions must be assigned to a reporting unit or units. Reporting units have been defined under the standards to be the same as or one level below an operating segment, as defined in SFAS No. 131, *Disclosures About Segments of an Enterprise and Related Information* ("SFAS No. 131"). As of December 31, 2006, the Company had total goodwill of \$6,722,725, of which \$4,672,435 was assigned to Delta Biologicals, the Company's Italian reporting unit, and \$2,050,290 was assigned to ImmunoVision, a component of the Company's domestic segment.

The Company tests goodwill for possible impairment on an annual basis and at any other time events occur or circumstances indicate that the carrying amount of goodwill may be impaired. During the third quarter of 2007, based principally upon a decline in the Company's market capitalization to less than its June 30, 2007 book value for the preceding seven weeks prior to the end of the third quarter of 2007, as well as the decision the Company made during the third quarter of 2007 to change its strategic direction and place any further development of the PARSEC® System on hold indefinitely, the Company determined that there was sufficient indication to require it to assess, in accordance with SFAS No. 142, whether any portion of its recorded goodwill balance was impaired.

The first step of the SFAS No. 142 impairment analysis consists of a comparison of the fair value of the reporting unit with its carrying amount, including the goodwill. The fair value was determined based on a combination of the income approach, which estimates the fair value based on the future discounted cash flows, and the market approach, which estimates the fair value based on market prices of comparable companies. Under the income approach, the Company assumed, with respect to Delta Biologicals, a forecasted cash flow period of five years, long-term annual growth rates of 5% and a discount rate of 17%, and, with respect to ImmunoVision, a forecasted cash flow period of five years, long-term annual growth rates of 5% and a discount rate of 16%. The Company also considered its total market capitalization as of September 30, 2007, using an average closing price for the 15 days prior to and the 15 days following September 30, 2007.

Based on the first step analysis that was separately performed for each of Delta Biologicals and ImmunoVision, the Company determined that the carrying amount of the goodwill at each of Delta Biologicals and ImmunoVision was in excess of its respective fair value. As such, the Company was required to perform the second step analysis for each of Delta Biologicals and ImmunoVision in order to determine the amount of the goodwill impairment. The second step analysis consisted of comparing the implied fair value of the goodwill with the carrying amount of the goodwill, with an impairment charge resulting from any excess of the carrying value of the goodwill over the implied fair value of the goodwill based on a hypothetical allocation of the estimated fair value of each of Delta Biologicals and ImmunoVision. Based on the second step analysis, the Company concluded that all \$4,672,435 of the goodwill recorded at Delta Biologicals and \$1,180,000 of the \$2,050,290 of goodwill recorded at ImmunoVision was impaired. As a result, the Company recorded a noncash goodwill impairment charge to operations totaling \$5,852,435 during the third quarter of 2007.

Additionally, in accordance with SFAS 142, the Company performed its annual test of goodwill using a measurement date of December 31, 2007 and no impairments were noted. However, a continued decline in the Company's market capitalization could require additional impairment charges to be recorded in future periods for the remaining goodwill for ImmunoVision.

The determination as to whether a write-down of goodwill is necessary involves significant judgment based on short-term and long-term projections of the Company. The assumptions supporting the estimated future cash flows of the reporting unit, including profit margins, long-term forecasts, discount rates and terminal growth rates, reflect the Company's best estimates.

Additionally, as discussed above in Note 3, *Write-off of PARSEC® Assets*, certain other long-lived assets, consisting of assets related to the PARSEC® System included in property, plant and equipment and equipment on lease, were assessed for impairment in accordance with SFAS No. 144 prior to the performance of the SFAS No. 142 analysis and were also determined to be impaired. During the third quarter of 2007, assets related to the PARSEC® System included in property and equipment were written down in the amount of \$337,912 and assets related to the PARSEC® System included in equipment on lease were written down by \$48,579. These charges were included in operating expenses in the accompanying statements of operations for the year ended December 31, 2007.

## 5 SEVERANCE COSTS

General and administrative expenses for the year ended December 31, 2007 include severance costs of \$1,998,400, which were accrued as a result of anticipated costs associated with management and other personnel changes that occurred in, or were being negotiated during, the fourth quarter of 2007. Included in this amount is the effect of a separation agreement and general release negotiated with Giorgio D'Urso in connection with his resignation, effective January 10, 2008, as President and Chief Executive Officer of the Company and as a member of the Board of Directors of the Company. Pursuant to this separation agreement, the Company paid Mr. D'Urso a one-time lump-sum payment of \$495,000, and the Company and Mr. D'Urso terminated his then existing employment agreement that provided for Mr. D'Urso to serve as President and Chief Executive Officer of the Company until February 24, 2010 and to receive a minimum annual base salary of \$348,519. Additionally, the remaining severance costs include estimated costs in connection with the terminations of selected employees of Delta Biologicals, the Company's Italian subsidiary, in 2007. Amounts that will eventually be paid in Italy will be subject to negotiations with the affected individuals and are subject to, and in some cases governed by, national collective and individual labor agreements existing in Italy.

## 6 CONCENTRATION OF CREDIT RISK

The Company performs periodic credit evaluations of its customers' financial condition and provides allowances for doubtful accounts as required.

The Company's accounts receivable are generated from sales made in the United States and Italy. As of December 31, 2007 and 2006, \$4,443,916 and \$5,476,166, respectively, of total net accounts receivable were due in Italy. At December 31, 2007 and 2006, 58.3% and 66.2%, respectively, of total net accounts receivable were due from hospitals and laboratories controlled by the Italian government. The Company maintains allowances for doubtful accounts, particularly in Italy where payment cycles are longer than in the United States, for potential credit losses based on the age of the accounts receivable and the results of the Company's periodic credit evaluations of its customers' financial condition. Additionally, the Company periodically receives payments based upon negotiated agreements with governmental regions in Italy, acting on behalf of hospitals located in the region, in satisfaction of previously outstanding accounts receivable balances (see Note 2, *Summary of Significant Accounting Policies*, under the heading of *Accounts Receivable and Allowance for Doubtful Accounts*).

Substantially all cash and cash equivalents and marketable securities are presently held at one international securities brokerage firm, UBS. Accordingly, the Company is subject to credit risk if this brokerage firm is unable to repay the balance in the account or deliver the Company's securities or if the brokerage firm should become bankrupt or otherwise insolvent.

## 7 PRODUCT LICENSE

In September 2004, the Company entered into a license agreement with an Italian diagnostics company to obtain a perpetual, worldwide, royalty-free license of product technology used by the Italian diagnostics company. This licensed hepatitis product technology is existing technology, which the Italian diagnostics company had developed and successfully commercialized to manufacture hepatitis products sold by them and for which it had already received "CE Marking" approval from the European Union. Through the acquisition of this existing technology in its current form, the Company also expects to be able to derive revenue from the manufacture and sale of new hepatitis products. In exchange for the Italian diagnostics company's assistance in transferring the know-how of the manufacturing technology, the Company agreed to pay a total of 1,000,000 Euro in the form of four milestone payments upon the Italian diagnostics company's achievement of certain enumerated performance objectives related to the transfer of such existing technology. In March 2005, the Company paid the first of these milestone payments, in the amount of \$277,717. As a result of the satisfaction of the first performance objective and the Company's corresponding payment of the first milestone payment, the Company determined that payment of the three remaining milestone payments was probable and, consequently,

an accrued license payable for the remaining 800,000 Euro was recorded during the first quarter of 2005. In September 2006, the three remaining performance objectives, and the corresponding milestone payments, were slightly postponed. The delay had no effect on the carrying value of the product license. Following the completion of the second performance objective, the second milestone payment of \$524,000 was made in December 2006 and the resulting accrued license payable in the accompanying consolidated balance sheet as of December 31, 2006 was \$526,800. Following the Italian diagnostics company's completion of the third performance objective, in October 2007, the Company paid the third milestone payment of \$438,000. The resulting accrued license payable in the accompanying consolidated balance sheet as of December 31, 2007 was \$147,184. The Company is now working with the Italian diagnostics company to achieve the remaining performance objective, which includes, among others, the condition for the Company to receive authorization for "CE Marking" in the European Union. The application for "CE Marking" was filed in January 2008, and the Company expects to pay the remaining license payable upon receipt of this approval, which is expected in the second quarter of 2008. The remaining performance objective also includes requirements that training be provided to the Company. This training has been, and will continue to be, expensed as incurred, and a corresponding amount will be recognized as a reduction to the product license recorded in the accompanying consolidated balance sheet. While the license is perpetual, the Company believes that the expected economic useful life of the license will be 4 to 6 years after the licensed technology has been transferred to the Company and the Company can utilize the licensed technology for its intended purpose, which will occur after the completion of all of the performance objectives and payment of the fourth milestone payment. Amortization of the product license will begin following the successful technology transfer to the Company and the initial sale of the hepatitis products manufactured by the Company.

## 8 INCOME TAXES

The Company accounts for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes* ("SFAS No. 109"). Under SFAS No. 109, deferred tax assets or liabilities are computed based upon the difference between the financial statement and income tax basis of assets and liabilities using the enacted marginal tax rate applicable when the related asset or liability is expected to be realized or settled. Deferred income tax expenses or benefits are based on the changes in the asset or liability from period to period. If available evidence suggests that it is more likely than not that some portion or all of the deferred tax assets will not be realized, then a valuation allowance is required to reduce the deferred tax assets to the amount that is more likely than not to be realized. Future changes in such valuation allowance would be included in the provision for deferred income taxes in the period of change.

The Company has established a full valuation allowance on its net domestic deferred tax assets, which are primarily comprised of net operating loss carryforwards. As of December 31, 2007 and 2006, the Company had no net domestic deferred tax asset, as domestic net operating losses generated prior to the merger between b2bstores.com and the pre-merger IVAX Diagnostics were utilized by IVAX and a full valuation allowance has been established against domestic deferred tax assets generated subsequent to March 14, 2001. As of December 31, 2007 and 2006, the Company had net deferred tax liabilities of \$174,708 and \$572,089, respectively, relating to tax deductible goodwill originally recorded in 2006 as a result of applying SAB 108 using the cumulative effect transition method (See Note 2, *Summary of Significant Accounting Policies*, under the heading of *Recently Issued Accounting Standards*). During the third quarter of 2007, as a result of the impairment charge relating to a portion of the goodwill recorded at ImmunoVision (See Note 4—*Impairment of Long-Lived Assets Including Goodwill*), the Company reduced its deferred tax liability relating to tax deductible goodwill at ImmunoVision and recorded a corresponding deferred tax benefit of \$460,200. Additionally, as of December 31, 2007 and 2006, the Company also had no net foreign deferred tax asset, as a full valuation allowance was provided during the first quarter of 2005 as a result of losses by the Company's Italian operation, and additional allowances have been provided for losses occurring since that date through December 31, 2007. Subsequent revisions to the estimated net realizable value of the deferred tax asset or deferred tax liability could cause the provision for income taxes to vary significantly from period to period.

The provision (benefit) for income taxes consists of the following:

	<u>Year Ended December 31,</u>	
	<u>2007</u>	<u>2006</u>
Current:		
Domestic .....	\$ —	\$ —
Foreign .....	68,612	89,887
Deferred:		
Domestic .....	(397,381)	63,492
Foreign .....	—	—
Total .....	<u>\$(328,769)</u>	<u>\$153,379</u>

The components of loss before income taxes are as follows:

	<u>Year Ended December 31,</u>	
	<u>2007</u>	<u>2006</u>
United States .....	\$ (1,447,645)	\$ (226,634)
Foreign .....	(9,314,863)	(2,228,221)
Total .....	<u>\$(10,762,508)</u>	<u>\$(2,454,855)</u>

The significant components of the net deferred income tax asset balances are as follows:

	<u>December 31,</u>	
	<u>2007</u>	<u>2006</u>
Current:		
Accounts receivable allowances .....	\$ 301,024	\$ 334,874
Reserves and accruals .....	1,234,539	309,846
Capitalized inventory costs .....	126,901	137,245
Valuation allowance .....	(1,662,464)	(781,965)
Deferred income taxes .....	—	—
Long-Term:		
Depreciation and basis differences on fixed assets .....	48,205	(197,431)
Stock based compensation .....	126,094	85,341
Other .....	(17,641)	(40,061)
Foreign net operating losses .....	4,006,332	1,269,445
Domestic net operating losses .....	3,770,473	3,855,493
Valuation allowance .....	(7,933,463)	(4,972,787)
Net deferred tax asset .....	<u>\$ —</u>	<u>\$ —</u>

The significant component of the net deferred income tax liability balance, as discussed above, is as follows:

	<u>December 31,</u>	
	<u>2007</u>	<u>2006</u>
Long-Term:		
Tax deductible goodwill .....	174,708	572,089
Net deferred tax liability .....	<u>\$174,708</u>	<u>\$572,089</u>

A reconciliation of the difference between the expected provision (benefit) for income taxes using the statutory U.S. Federal tax rate and the Company's actual provision (benefit) is as follows:

	Year Ended December 31,	
	2007	2006
Provision (benefit) for income taxes at U.S. Federal statutory rate of 35% .....	\$(3,766,878)	\$(859,199)
Change in valuation allowance (excluding portion relating to stock options) .....	3,355,666	923,829
Foreign tax rate differential and global permanent differences .....	82,443	88,749
Provision (benefit) for income taxes .....	<u>\$ (328,769)</u>	<u>\$ 153,379</u>

The Company's income tax provision or benefit for the years ended December 31, 2007 and 2006 was different from the amount computed on the loss before provision (benefit) for income taxes at the statutory rate of 35% primarily due to changes in the valuation allowance, foreign tax rate differential and global permanent differences, as well as the deferred tax benefit recorded as a result of the goodwill impairment charge relating to ImmunoVision.

As discussed above, the Company has established a full valuation allowance on its net domestic deferred tax assets, which are primarily comprised of net operating loss carryforwards and, in 2005, provided a full valuation allowance on the foreign net deferred income tax assets. During the years ended December 31, 2007 and 2006, the Company increased its valuation allowance by approximately \$3,841,000 and \$1,078,000, respectively. Net operating losses generated by the Company after March 14, 2001 total \$9,668,000, of which \$4,010,000 are available for use prior to their expiration in 2021. Additionally, net operating losses of \$1,595,000, \$350,000, \$710,000, \$2,514,000, \$459,000 and \$30,000 are available for use prior to their expirations in 2022, 2023, 2024, 2025, 2026 and 2027, respectively. Approximately \$3,710,000 of the domestic net operating loss at December 31, 2007, representing approximately \$1,300,000 (including approximately \$0 and \$10,000 for the years ended December 31, 2007 and 2006, respectively) of the valuation allowance, relates to the benefit of stock options exercised which have not yet been credited to additional paid-in capital. The net operating losses included in the foreign net deferred tax asset will begin to expire in 2009.

The Company's net operating loss carryforwards may be limited in the future as a result of the acquisition of IVAX by Teva.

United States income taxes have not been provided on undistributed earnings of foreign subsidiaries, as such earnings are being retained indefinitely by such subsidiaries for reinvestment. The distribution of these earnings would first reduce the domestic valuation allowance before resulting in additional United States income taxes.

## 9 EMPLOYEE BENEFIT PLAN

Beginning after the date of the merger between b2bstores.com and the pre-merger IVAX Diagnostics, the Company established its own 401(k) employee savings plan which allows for pre-tax employee payroll contributions and discretionary employer matching contributions. Matching contributions of \$72,000 and \$71,000 were made into this plan during the years ended December 31, 2007 and 2006, respectively.

## 10 ACCRUED EXPENSES

Accrued expenses consist of the following:

	December 31,	
	2007	2006
Payroll costs .....	\$ 775,346	\$ 834,366
Severance and related costs (Note 5) .....	2,459,372	—
Taxes, other than income taxes .....	1,287,853	1,512,977
Professional fees .....	249,853	365,769
Royalties .....	96,415	81,995
Other .....	535,533	253,178
	<u>\$5,404,372</u>	<u>\$3,048,285</u>

## 11 SHAREHOLDERS' EQUITY

### *Common Stock*

On March 14, 2001, b2bstores.com, IVAX and the pre-merger IVAX Diagnostics consummated a merger of the pre-merger IVAX Diagnostics into b2bstores.com pursuant to which all of the issued and outstanding shares of the pre-merger IVAX Diagnostics were converted into 20,000,000 shares of b2bstores.com stock and b2bstores.com's name was changed to "IVAX Diagnostics, Inc."

Concurrent with the approval of the merger between b2bstores.com and the pre-merger IVAX Diagnostics, the Company amended its certificate of incorporation to increase the number of shares of authorized common stock from 25,000,000 to 50,000,000.

### *Share Repurchase Program*

During May 2002, the Company's Board of Directors approved a program to repurchase up to 1,000,000 shares of the Company's publicly held common stock. In December 2002, the Company's Board of Directors authorized an additional repurchase of up to 1,000,000 shares of the Company's publicly held common stock. During 2007 and 2006, the Company did not repurchase any shares of its common stock. The total number of shares of common stock repurchased by the Company since the inception of its repurchase program is 1,184,573.

### *Pre-merger IVAX Diagnostics and b2bstores.com Employee Options and Stock Purchase Arrangements*

On September 30, 1999, the Board of Directors and stockholders of b2bstores.com approved the 1999 Performance Equity Plan (the "Performance Plan"). The Performance Plan authorizes the grant of up to 2,000,000 shares of common stock to key employees, officers, directors and consultants. Both incentive and non-qualified options may be issued under the Performance Plan. As of December 31, 2006, no options granted prior to the merger between b2bstores.com and the pre-merger IVAX Diagnostics were outstanding under the Performance Plan following the March 2006 exercise of 8,333 options granted at an exercise price of \$2.56 per share. Options granted prior to the merger between b2bstores.com and the pre-merger IVAX Diagnostics to employees of b2bstores.com who never became employees of the surviving company were not included in the information presented elsewhere in Note 2, *Summary of Significant Accounting Policies*, Note 11, *Shareholders' Equity*, or in the Company's calculations made in connection with the adoption of SFAS 123(R). Prior to the creation of the Performance Plan, options to purchase an additional 1,000,000 shares of common stock were granted by the Board of Directors of b2bstores.com to certain of its former officers. No options granted by b2bstores.com prior to the creation of the Performance Plan are outstanding at December 31, 2007.

### *Stock Option Plans*

The Company maintains two stock option plans. The first, the IVAX Diagnostics, Inc. 1999 Stock Option Plan (the "1999 Plan"), became effective June 29, 1999 when approved by the Board of Directors and the sole stockholder of the pre-merger IVAX Diagnostics. The 1999 Plan permits the issuance of options to employees, non-employee directors and consultants to purchase up to 2,000,200 shares of the Company's common stock. At the effective time of the merger between b2bstores.com and the pre-merger IVAX Diagnostics, automatically and without any action on the part of an option holder, the surviving company assumed the 1999 Plan and each outstanding option granted under the 1999 Plan as an option to purchase shares of the surviving company's common stock under the same terms and conditions as the outstanding option. During 2006, the Company received \$13,140 and issued 18,000 shares of common stock with an intrinsic value of \$22,860 as a result of the exercise of the remaining 18,000 options to purchase shares of the Company's common stock under the 1999 Plan. As of December 31, 2006, no options to purchase shares of the Company's common stock were outstanding under the 1999 Plan. The Company does not have any current intention of issuing any additional stock options under the 1999 Plan.

The Company's second stock option plan was created on September 30, 1999 when the Board of Directors and stockholders of b2bstores.com approved the Performance Plan. The Performance Plan authorizes the grant of up to 2,000,000 shares of common stock of the Company to key employees, officers, directors and consultants. Both incentive and non-qualified options may be issued under the Performance Plan. As of December 31, 2007, 784,949 options to purchase shares of the Company's common stock were outstanding under the Performance Plan. During the year ended December 31, 2007, under the Performance Plan, there were no exercises of stock options, 100,000 options with a fair value at the date of grant of \$0.71 per share that vested immediately and were exercisable over a ten year period were granted, and 134,600 options were terminated. During the year ended December 31, 2006, under the Performance Plan, no options were exercised, 100,000 options with a fair value at the date of grant of \$1.15 per share that vested immediately and were exercisable over a ten year period were granted, and 1,650 options were terminated.

Valuations are based on highly subjective assumptions about the future, including stock price volatility and exercise patterns. The fair value of share-based payment awards was estimated using the Black-Scholes option pricing model. Expected volatilities are based on the historical volatility of the Company's stock. The Company uses historical data to estimate option exercise and employee terminations. The expected term of options granted represents the period of time that options granted are expected to be outstanding. The risk-free rate for periods within the expected life of the option is based on the U.S. Treasury yield curve in effect at the time of the grant.

Options granted under these option plans were granted at an option exercise price equal to the closing market value of the stock on the date of the grant and with vesting, primarily for Company employees, all at once after seven years or in equal annual amounts over a four year period, and, primarily for non-employee directors, immediately.

The following charts summarize option activity as of December 31, 2007 and changes during the years ended December 31, 2007 and 2006 under the Performance Plan for options granted by the Company after the consummation of the merger between b2bstores.com and the pre-merger IVAX Diagnostics, as well as transactions under the 1999 Plan:

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2005 .....	739,199	\$4.22
Granted .....	100,000	\$1.56
Terminated .....	(1,650)	\$2.40
Exercised .....	(18,000)	\$0.73
Outstanding at December 31, 2006 .....	819,549	\$3.97
Granted .....	100,000	\$1.00
Terminated .....	(134,600)	\$3.58
Exercised .....	—	\$ —
Outstanding at December 31, 2007 .....	<u>784,949</u>	<u>\$3.66</u>
Options exercisable at December 31, 2007 .....	<u>674,486</u>	<u>\$3.72</u>

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$1.00	100,000	9.6	\$1.00	100,000	\$1.00
\$1.35 - \$2.40	178,100	5.5	\$1.79	178,100	\$1.79
\$2.88 - \$3.00	130,000	0.2	\$2.97	35,000	\$2.88
\$4.35 - \$4.91	160,000	7.5	\$4.37	150,000	\$4.37
\$5.20 - \$7.12	216,849	3.3	\$6.33	211,386	\$6.31
	<u>784,949</u>	4.9	\$3.66	<u>674,486</u>	\$3.72

The aggregate intrinsic value for the outstanding and exercisable in-the-money options was \$0 at December 31, 2007. In August 2007, the Company granted under the Performance Plan 100,000 options with an exercise price of \$1.00 and a fair value at the date of grant of \$0.71. These options vested immediately upon grant and are exercisable over a ten-year period.

A summary of the status of the Company's non-vested options as of December 31, 2007 and changes during the year ended December 31, 2007 is presented below:

<u>Non-vested Options</u>	Number of Shares	Weighted Average Grant-date Fair Value
Outstanding at December 31, 2006 .....	211,925	\$2.83
Granted .....	100,000	\$0.72
Vested .....	(110,962)	\$1.04
Terminated .....	(90,500)	\$2.80
Exercised .....	—	—
Outstanding at December 31, 2007 .....	<u>110,463</u>	<u>\$2.75</u>

As of December 31, 2007, there was \$38,000 of unrecognized compensation costs, based on the fair value of unvested awards, related to non-vested share-based compensation arrangements granted under the Performance Plan. This cost is expected to be recognized over a weighted average period of 0.8 years. No windfall tax benefits were recognized during the years ended December 31, 2007 or 2006.

## 12 SEGMENT INFORMATION

The Company's management reviews financial information, allocates resources and manages its business by geographic region. The Domestic region, which includes corporate expenditures, contains the Company's subsidiaries in the United States. The Italian region contains the Company's subsidiary located in Italy. The information provided is based on internal reports and was developed and utilized by management for the sole purpose of tracking trends and changes in the results of the regions. The information, including the allocations of expense and overhead, was calculated based on a management approach and may not reflect the actual economic costs, contributions or results of operations of the regions as stand-alone businesses. If a different basis of presentation or allocation were utilized, the relative contributions of the regions might differ but the relative trends would, in management's view, likely not be materially impacted. The table below sets forth net revenues, income (loss) from operations, total assets and goodwill by region for the years ended December 31, 2007 and 2006:

	<u>Domestic</u>	<u>Italian</u>	<u>Eliminations</u>	<u>Total</u>
December 31, 2007:				
External net sales .....	\$13,726,958	\$ 6,248,912	\$ —	\$ 19,975,870
Intercompany sales .....	858,921	445,171	(1,304,092)	—
Net revenue .....	<u>\$14,585,879</u>	<u>\$ 6,694,083</u>	<u>\$(1,304,092)</u>	<u>\$ 19,975,870</u>
Loss from operations .....	<u>\$(1,998,668)</u>	<u>\$(9,304,074)</u>	<u>\$ (14,856)</u>	<u>\$(11,317,598)</u>
Assets .....	<u>\$16,270,801</u>	<u>\$ 9,497,531</u>	<u>\$ —</u>	<u>\$ 25,768,332</u>
Goodwill .....	<u>\$ 870,290</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 870,290</u>
December 31, 2006:				
External net sales .....	\$13,065,708	\$ 6,457,763	\$ —	\$ 19,523,471
Intercompany sales .....	1,042,152	366,687	(1,408,839)	—
Net revenue .....	<u>\$14,107,860</u>	<u>\$ 6,824,450</u>	<u>\$(1,408,839)</u>	<u>\$ 19,523,471</u>
Income (loss) from operations .....	<u>\$ (823,860)</u>	<u>\$(2,086,664)</u>	<u>\$ 36,167</u>	<u>\$ (2,874,357)</u>
Assets .....	<u>\$17,753,722</u>	<u>\$15,953,380</u>	<u>\$ —</u>	<u>\$ 33,707,102</u>
Goodwill .....	<u>\$ 2,050,290</u>	<u>\$ 4,672,435</u>	<u>\$ —</u>	<u>\$ 6,722,725</u>

### 13 COMMITMENTS AND CONTINGENCIES

#### *Leases*

Certain of the Company's office, plant and warehouse facilities are leased by the Company under non-cancelable operating leases. Rent expense for the years ended December 31, 2007 and 2006 totaled \$613,985 and \$513,480, respectively. The future minimum lease payments under non-cancelable capital leases and their related assets recorded at December 31, 2007 and 2006 were not material. The future minimum lease payments under non-cancelable operating leases with initial or remaining terms of one year or more at December 31, 2007 were as follows:

2008 .....	\$ 555,000
2009 .....	437,000
2010 .....	394,000
2011 .....	381,000
2012 .....	—
Thereafter .....	—
Total minimum lease payments .....	<u>\$1,767,000</u>

#### *Litigation, Claims and Assessments*

The Company is involved in various legal claims and actions and regulatory matters, and other notices and demand proceedings arising in the ordinary course of business. While it is not possible to predict or determine the outcome of these proceedings, in the opinion of management, based on a review with legal counsel, any losses resulting from such legal proceedings would not have a material adverse impact on the financial position, results of operations or cash flows of the Company.

### 14 RELATED PARTY TRANSACTIONS

Prior to, and for a short time after, Teva's acquisition of IVAX, the Company, as a subsidiary of IVAX, had directors and officers insurance as well as property insurance coverage that fell within the scope of IVAX' directors and officers insurance and property insurance policies. Beginning in 2006, the Company purchased its own directors and officers insurance and property insurance policies and, accordingly, no longer falls within the scope of Teva's or IVAX' directors and officers insurance or property insurance policies.

## 15 QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following table summarizes selected quarterly data of the Company for the years ended December 31, 2007 and 2006 (in thousands except per share data):

	First Quarter	Second Quarter	Third Quarter <sup>(1)(2)</sup>	Fourth Quarter <sup>(3)</sup>	Full Year
<b>2007</b>					
Net revenue .....	\$4,946	\$5,121	\$ 4,972	\$ 4,937	\$ 19,976
Gross profit .....	2,988	2,980	2,762	2,846	11,576
Loss from operations .....	(292)	(580)	(8,391)	(2,055)	(11,318)
Net loss .....	(238)	(463)	(7,841)	(1,892)	(10,434)
Basic and diluted net loss per share .....	(0.01)	(0.02)	(0.28)	(0.07)	(0.38)
<b>2006</b>					
Net revenue .....	\$4,718	\$5,363	\$ 4,852	\$ 4,590	\$ 19,523
Gross profit .....	2,734	2,970	2,687	2,675	11,066
Loss from operations .....	(689)	(217)	(1,292)	(676)	(2,874)
Cumulative effect of change in accounting principle .....	(201)	—	—	—	(201)
Net loss .....	(797)	(118)	(1,268)	(626)	(2,809)
Cumulative effect of change in accounting principle per basic and diluted common share .....	(0.01)	—	—	—	(0.01)
Basic and diluted net loss per share .....	(0.03)	(0.01)	(0.05)	(0.02)	(0.10)

- (1) Includes the effect of the write-off of certain PARSEC<sup>®</sup> related assets in 2006 and 2007 as discussed in Note 3, *Write-off of Certain PARSEC<sup>®</sup> Assets*.
- (2) Includes the effect of the write-off of goodwill relating to both Delta Biologicals and ImmunoVision in 2007 as discussed in Note 4, *Impairment of Long-Lived Assets Including Goodwill*.
- (3) Includes the effect of severance costs in 2007 as discussed in Note 5, *Severance Costs*.

Basic and diluted net loss per share for each of the quarters presented above is based on the respective weighted average number of shares for the quarters. The sum of the quarters may not necessarily be equal to the full year basic and diluted net loss per share amounts due to the effects of rounding.

## 16 SUBSEQUENT EVENT

Subsequent to December 31, 2007, all \$6,025,000 of the Company's portfolio of marketable securities held at December 31, 2007 were sold through the Dutch auction process, with \$1,925,000 of the proceeds then invested in other select short-term marketable security investments and \$4,100,000 of the proceeds reinvested in auction rate securities. However, recent uncertainties in the global credit and capital markets have prevented sellers of auction rate securities, including the Company, from liquidating their holdings in auction rate securities. Since mid-February 2008, each of the remaining \$4,100,000 of auction rate securities that the Company held experienced, and has continued to experience, failed auctions. As described in Note 2, *Summary of Significant Accounting Policies*, under the heading of *Marketable Securities*, as a result of these failed auctions, the Company has been unable to liquidate its investment and does not expect to be able to access its funds that are invested in these auction rate securities until a future auction of these securities is successful or a secondary market develops for these particular securities. The Company included these \$4,100,000 of auction rate securities in long-term marketable securities in the accompanying consolidated balance sheet as of December 31, 2007 because it cannot predict when future auctions related to these securities will be successful or when the Company will be able to otherwise liquidate its investment. The Company believes that these auction rate securities are not impaired at December 31, 2007 because all of the securities held were successful at auction in January 2008. The Company continues to earn interest at the maximum or default contractual rate on these auction rate securities as a result of their auction failures.

On March 31, 2008, the Company received notification that the investment bank holding its auction rate securities will value these securities at approximately \$3,912,000, or 95.43% of par value, based upon an internal valuation model developed by the investment bank. This valuation model considered for each security such factors as liquidity, credit rating, underlying collateral, final maturity and applicable insurance when estimating value. Based upon this information, the Company may recognize a temporary reduction to its shareholders' equity in its financial statements as of and for the quarter ending March 31, 2008. The Company continues to expect to hold these securities until such time as it is able to receive at least par value for its investments, which, given the current uncertainty in the credit markets, the Company expects will be longer than 12 months.

All of the auction rate securities held by the Company are secured by pools of student loans, in excess of 90% of which are guaranteed under FFELP, and each security had a credit rating of AAA or Aaa when purchased. The Company does not own, and has not invested in, any auction rate securities secured by mortgages or collateralized debt.

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

Previously reported.

#### **ITEM 9A(T). CONTROLS AND PROCEDURES**

##### *Evaluation of Disclosure Controls and Procedures*

As of the end of the period covered by this Annual Report on Form 10-K, our management evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934). Based upon that evaluation, our principal executive officer and principal financial officer concluded that our disclosure controls and procedures are effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Securities Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms and is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

##### *Management's Report on Internal Control over Financial Reporting*

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934). Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP and includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

As of the end of the period covered by this Annual Report on Form 10-K, our management evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness of our internal control over financial reporting. This evaluation was conducted using the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based upon that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2007.

Pursuant to temporary rules of the Securities and Exchange Commission, our management's report on internal control over financial reporting is furnished with this Annual Report on Form 10-K and shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities of that section, nor shall it be deemed to be incorporated by reference in any filing under the Securities Act of 1933 or Securities Exchange Act of 1934.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding our internal control over financial reporting. Our management's report on internal control over financial reporting was not subject to attestation by our independent registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only our management's report on internal control over financial reporting in this Annual Report on Form 10-K.

*Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2007 that would have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.

**PART III**

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

*Directors and Executive Officers*

The following table sets forth information with respect to our directors and our executive officers as of March 26, 2008.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Kevin D. Clark . . . . .	45	Acting Chief Executive Officer and Chief Operating Officer
Duane M. Steele . . . . .	57	Vice President—Business Development
Mark S. Deutsch . . . . .	45	Chief Financial Officer and Vice President—Finance
Itzhak Krinsky, Ph.D. . . . .	55	Chairman of the Board of Directors
Mark W. Durand . . . . .	48	Director
Richard S. Egosi . . . . .	45	Director
Fernando L. Fernandez . . . . .	47	Director
Glenn L. Halpryn . . . . .	47	Director
John B. Harley, M.D. . . . .	58	Director
Jose J. Valdes-Fauli . . . . .	56	Director

Set forth below are the names, ages, positions held and business experience, including during the past five years, of our directors and our executive officers as of March 26, 2008. Officers serve at the discretion of the board of directors. There is no family relationship between any of the directors or executive officers and there is no arrangement or understanding between any director or executive officer and any other person pursuant to which the director or executive officer was selected.

Mr. Kevin D. Clark, age 45, was appointed as our acting Chief Executive Officer in January 2008. Mr. Clark has served as our Chief Operating Officer since September 2007 and as Chief Operating Officer of ImmunoVision since 1987. He also served as President of ImmunoVision from 1987 through 1995. Mr. Clark was a founding member of the Arkansas Biotech Association and, from 1995 through 2004, served as its Executive Vice President, and in 2002, served as its President. Since 2003, Mr. Clark has served as a member of the Executive Committee of the University of Arkansas Technology Development Foundation, a non-profit foundation for the commercialization of technology developed at the University of Arkansas in Fayetteville. From 2000 to 2003, Mr. Clark was a member of the Advisory Board of Arkansas BioVentures, a state and federally funded incubator program for biotechnology.

Mr. Duane M. Steele, age 57, has served as our Vice President—Business Development since the merger with the pre-merger IVAX Diagnostics in 2001 and had served in the same capacity with the pre-merger IVAX Diagnostics since 1996. He joined Diamedix in 1995 and has over 30 years of diagnostics industry experience. He has served as the Chief Operating Officer of Diamedix since 1997. From 1995 to 1997, he served as Vice President—Business Development of Diamedix. From 1990 to 1994, he served as President and Chief Executive Officer of LaserCharge, Inc. in Austin, Texas. From 1988 to 1989, Mr. Steele was the General Manager of Austin Biological Laboratories, Inc. From 1972 to 1987, Mr. Steele held a variety of positions with Kallestad Diagnostics, Inc., including Senior Vice President.

Mr. Mark S. Deutsch, age 45, has served as our Chief Financial Officer and Vice President—Finance since the merger with the pre-merger IVAX Diagnostics in 2001 and had served in the same capacities with the pre-merger IVAX Diagnostics since 1996. He has served as the Vice President—Finance of Diamedix since 1993 and has 14 years of diagnostics industry experience. From 1988 to 1993, Mr. Deutsch held various positions including Accounting Manager of IVAX and Controller of certain subsidiaries of IVAX. From 1985 to 1988, Mr. Deutsch worked for Arthur Andersen & Co. as a Senior Accountant.

Dr. Itzhak Krinsky, age 55, has served as the Chairman of our Board of Directors since April 2006. He has served as Corporate Vice President for Business Development of Teva since May 2005. Dr. Krinsky was a managing director with The Silverfern Group, Inc. from January 2003 until February 2005 and, until joining Teva, a managing director with Trenwith Securities, LLC, both investment banking boutiques in New York City. From July 2001 until December 2002, Dr. Krinsky was a managing director of Krinsky, Financial & Investment Consulting in New York City and, from January 1998 until June 2001, a senior strategist with the Investment Banking Research and Strategy Group of Bankers Trust (the predecessor of Deutsche Bank Securities) and later a managing director in the Acquisition and Corporate Advisory Group of Deutsche Bank Securities in New York City. Dr. Krinsky's academic career includes a position as Professor of Finance & Business Economics, Michael G. DeGroote School of Business, McMaster University, Canada and as a visiting professor in Institute for International Studies and Training of Japan, Kamiide, Japan, Nankai University, Tianjin The Peoples Republic of China and the Leonard N. Stern School of Business at New York University, as well as extensive publications in leading academic journals. Dr. Krinsky is currently a member of the Board of Directors of Can-fite Biopharma Ltd. From 2005 through 2007, Dr. Krinsky served as a member of the Board of Directors of Advanced Vision Technology (A.V.T.) Ltd. and, from July 2007 through December 2007, he served as a member of the Board of Directors of Eldav Investment Ltd. Dr. Krinsky received his B.A. and M.A. in economics from Tel Aviv University in 1976 and 1978, respectively, and his Ph.D. in economics from McMaster University in 1983.

Mr. Mark W. Durand, age 48, has served as a director since April 2006. Since November 2007, Mr. Durand has served as Senior Vice President and Chief Financial Officer of Watson Pharmaceuticals, Inc. From 2004 until November 2007, Mr. Durand served as Chief Financial Officer and Senior Vice President—Finance and Business Development of Teva North America. Prior to joining Teva North America, Mr. Durand served in various executive management roles in finance, business development and general management at Bristol-Myers Squibb Company, including in 2002 as Vice President—Finance and Business Development and in 2004 he was also appointed Vice President—Specialty Pharmaceuticals. Mr. Durand also currently serves as a member of the Board of Directors of the Dartmouth College Graduate Studies Program. Mr. Durand received a B.S. from Duke University, M.S. from Dartmouth College and M.B.A. from the University of Chicago.

Mr. Richard S. Egosi, age 45, has served as a director since April 2006. Since 1999, Mr. Egosi has served as Senior Vice President and General Counsel of Teva North America and Latin America, overseeing the legal function for the Teva group of companies in the Americas. From 1995 to 1999, Mr. Egosi served as Associate General Counsel of Teva. From 1988 to 1995, Mr. Egosi was an attorney in private practice. Mr. Egosi received a J.D. and M.B.A. from Emory University, and a B.S. in economics from Clemson University.

Mr. Fernando L. Fernandez, age 47, has served as a director since April 2005. Mr. Fernandez serves as Senior Vice President—Finance, Chief Financial Officer, Treasurer and Secretary of Continucare Corporation.

Mr. Fernandez, a certified public accountant, served as Senior Vice President—Finance, Chief Financial Officer, Treasurer and Secretary of Whitman Education Group, Inc. from 1996 until 2003. From August 1991 through February 1996 and from August 2003 through June 2004, Mr. Fernandez served as Chief Financial Officer of several private investment entities owned by Phillip Frost, M.D. Prior to 1991, Mr. Fernandez served as Audit Manager for PricewaterhouseCoopers LLP (formerly Coopers & Lybrand) in Miami, Florida.

Mr. Glenn L. Halpryn, age 47, has served as a director since December 2002. Mr. Halpryn has been Chief Executive Officer of Transworld Investment Corporation since June 2001 and the President of Chelsea Management Corporation since September 2004. Mr. Halpryn has been President and Chief Executive Officer and a member of the Boards of Directors of Getting Ready Corporation and ClickNSettle.com, Inc., public acquisition companies, since December 2006 and September 2007, respectively. From April 2001 through December 2006, Mr. Halpryn served as Chairman of the Board of Directors and President of Orthodontix, Inc., a public acquisition company whose business combination was effected in December 2006 with Protalix, Ltd. Since January 1987, Mr. Halpryn has been a portfolio manager of International Venture Capital, Ltd. Since February 1987, Mr. Halpryn has been the President of United Security Corporation, a broker-dealer registered with the NASD. Since 1984, Mr. Halpryn has been engaged in real estate investment and development activities, including the management, finance and leasing of commercial real estate. From November 1984 through June 2001, Mr. Halpryn served as Vice President of Transworld Investment Corporation. From April 1988 through June 1998, Mr. Halpryn was Vice Chairman of Central Bank, a Florida state-chartered bank. From November 1995 through April 1998, Mr. Halpryn served as Chairman and President of Embassy Acquisition Corp. From June 1992 through May 1994, Mr. Halpryn served as the Vice President, Secretary and Treasurer and as a director of Frost Hanna Halpryn Capital Group, Inc., a “blank check” company whose business combination was effected in May 1994 with Sterling Healthcare Group, Inc.

Dr. John B. Harley, age 58, has served as a director since the merger with the pre-merger IVAX Diagnostics in 2001. He has held various positions at the University of Oklahoma Health Sciences Center since 1982. In the Department of Medicine, his positions include Chief of Rheumatology, Allergy and Immunology Section and Vice Chair for Research, George Lyna Cross Research Professor (1999 to present), James R. McEldowney Chair in Immunology and Professor of Medicine (1992 to present), Associate Professor (1986 to 1992) and Assistant Professor (1982 to 1986). Since 1996, Dr. Harley has been an Adjunct Professor in the Department of Pathology. In the Department of Microbiology, Dr. Harley has served as Adjunct Professor (1992 to present), Adjunct Associate Professor (1988 to 1992) and Adjunct Assistant Professor (1983 to 1988). Since 1982, Dr. Harley has also been associated with the Oklahoma Medical Research Foundation’s Arthritis and Immunology Program as Program Head (1999 to present), Member (1998 to present), Associate Member (1989 to present), Affiliated Associate Member (1986 to 1989) and Affiliated Assistant Member (1982 to 1986). Dr. Harley has also served as a Staff Physician (1982, 1984 to 1987 and 1992 to present) and a Clinical Investigator (1987 to 1992), Immunology Section, Medical Service at the Veterans Affairs Medical Center, Oklahoma City, Oklahoma. In 1981 and 1982, Dr. Harley was a Postdoctoral Fellow in Rheumatology with the Arthritis Branch of the National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases, National Institute of Health, Bethesda, Maryland. He was also a Clinical Associate at the Laboratory of Immunoregulation, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland from 1979 to 1982. Dr. Harley is also the Secretary and a member of the Board of Directors of JK Autoimmunity, Inc., as well as the Secretary and Treasurer and a member of the Boards of Directors of Dynamic Ventures, Inc. and VRB Associates, Inc.

Mr. Jose J. Valdes-Fauli, age 56, has served as a director since December 2002. Since January 2008, Mr. Valdes-Fauli has served as the President and Chief Executive Officer of The International Bank of Miami. From 2004 through December 2006, Mr. Valdes-Fauli served as the President and Chief Executive Officer of Beach Bank. From 1998 to 2003, Mr. Valdes-Fauli was the President and Chief Executive Officer of Colonial Bank—South Florida Region, an affiliate of Colonial BancGroup. Mr. Valdes-Fauli has been involved in the banking industry for over 31 years. He is a member of the Florida International University Foundation Board of Directors. He is also Director Emeritus of the Florida Grand Opera and a director of the Bass Museum of Art, the

Concert Association of Florida and the Mercy Hospital Foundation. Mr. Valdes-Fauli is also a member of the Advisory Board of New Hope Charities, Inc. and a member of the Miami-Dade County Cultural Affairs Council.

#### *Section 16(a) Beneficial Ownership Reporting Compliance*

Section 16(a) of the Securities Exchange Act of 1934 requires our directors, executive officers and 10% stockholders to file initial reports of ownership and reports of changes in ownership of our common stock and other equity securities with the Securities and Exchange Commission and the American Stock Exchange. Our directors, executive officers and 10% stockholders are required to furnish us with copies of all Section 16(a) reports they file. Based on a review of the copies of such reports furnished to us and written representations from our directors and executive officers that no other reports were required, we believe that our directors, executive officers and 10% stockholders complied with all Section 16(a) filing requirements applicable to them for the year ended December 31, 2007.

#### *Code of Conduct and Ethics*

Our Board of Directors has adopted a Code of Conduct and Ethics, which applies to all of our directors, officers and employees, and a code of ethics, also known as a Senior Financial Officer Code of Ethics, which applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The Code of Conduct and Ethics and the Senior Financial Officer Code of Ethics are posted in the "Investor Relations" section of our Internet web site at [www.ivaxdiagnostics.com](http://www.ivaxdiagnostics.com). If we make an amendment to, or grant a waiver with respect to, any provision of the Senior Financial Officer Code of Ethics, then we intend to disclose the nature of such amendment or waiver by posting it in the "Investor Relations" section of our Internet web site at [www.ivaxdiagnostics.com](http://www.ivaxdiagnostics.com) or by other appropriate means as required or permitted under the applicable regulations of the Securities and Exchange Commission and rules of the American Stock Exchange.

#### *Audit Committee Members and Financial Expert*

The members of the Audit Committee of our Board of Directors are Fernando L. Fernandez, Glenn L. Halpryn and Jose J. Valdes-Fauli. Our Board of Directors has determined that each of Messrs. Fernandez and Valdes-Fauli has the attributes, education and experience of, and therefore is, an "audit committee financial expert," as such term is defined in Item 407(d)(5) of Regulation S-K, and that each of Messrs. Fernandez and Valdes-Fauli is "independent," as such term is defined in the applicable regulations of the Securities and Exchange Commission and rules of the American Stock Exchange relating to directors serving on audit committees.

## ITEM 11. EXECUTIVE COMPENSATION

### Compensation of Named Executive Officers

#### Summary Compensation Table

The following table sets forth certain summary information concerning compensation which we paid or accrued to or on behalf of each of our executive officers during the fiscal years ended December 31, 2007 and 2006 (the "Named Executive Officers") for each of such fiscal years.

Name and Principal Position	Year	Salary	Bonus	Stock Awards	Option Awards <sup>(3)</sup>	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Giorgio D'Urso, <sup>(1)</sup> Former Chief Executive Officer	2007	\$348,519	—	—	—	—	—	\$495,000 <sup>(4)</sup>	\$843,519
	2006	\$348,519	—	—	—	—	—	—	\$348,519
Kevin D. Clark, <sup>(2)</sup> Acting Chief Executive Officer and Chief Operating Officer	2007	\$128,784	—	—	—	—	—	\$ 3,864 <sup>(5)</sup>	\$132,648
	2006	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Duane M. Steele, Vice President— Business Development	2007	\$216,888	—	—	\$10,587	—	—	\$ 6,507 <sup>(5)</sup>	\$233,982
	2006	\$179,038	—	—	\$23,730	—	—	\$ 5,371	\$208,139
Mark S. Deutsch, Chief Financial Officer	2007	\$128,625	—	—	\$ 4,636	—	—	\$ 3,859 <sup>(5)</sup>	\$137,120
	2006	\$125,327	—	—	\$12,520	—	—	\$ 3,760	\$141,607

- (1) Mr. D'Urso served as our Chief Executive Officer and President until his resignation from such positions, effective January 10, 2008. Mr. D'Urso was party to an employment agreement which provided for him to serve as our Chief Executive Officer and President until February 24, 2010 and to receive a minimum annual base salary of \$348,519. In connection with Mr. D'Urso's resignation as our Chief Executive Officer and President, effective January 10, 2008, we and Mr. D'Urso mutually agreed to terminate his employment agreement and entered into a separation agreement and mutual release, pursuant to which we paid Mr. D'Urso a one time lump-sum payment of \$495,000. The terms of Mr. D'Urso's employment agreement and the separation agreement and general release between us and Mr. D'Urso are described in further detail below under "Potential Payments upon Termination or Change-in-Control."
- (2) Mr. Clark was appointed as our Chief Operating Officer, effective September 17, 2007, and our acting Chief Executive Officer, effective January 10, 2008. Throughout the fiscal year ended December 31, 2007, Mr. Clark served as, and Mr. Clark continues to serve as, the Chief Operating Officer of ImmunoVision. Accordingly, pursuant to the rules and regulations of the Securities and Exchange Commission, the compensation information set forth with respect to Mr. Clark includes (a) for the period from January 1, 2007 through September 16, 2007, compensation paid or accrued by us to or on behalf of Mr. Clark for his services as Chief Operating Officer of ImmunoVision and (b) for the period from September 17, 2007 through December 31, 2007, compensation paid or accrued by us to or on behalf of Mr. Clark for his services as our Chief Operating Officer and as Chief Operating Officer of ImmunoVision.
- (3) Represents the dollar amount recognized for financial statement reporting purposes for the fiscal year ended December 31, 2007, in accordance with FAS 123(R), without taking into account an estimate of forfeitures related to service-based vesting, of stock option grants, including amounts from awards granted prior to 2007. Assumptions used in the calculation of these amounts are included in Note 11 to our Consolidated Financial Statements,

*Shareholders' Equity.* There were no forfeitures during 2007. The amount also includes the effect of a cumulative effect adjustment recorded as a result of the change in classification of certain stock options to a liability award grant in accordance with FAS 123(R), as well as fair value adjustments that occurred during the fiscal year ended December 31, 2007 to that liability award.

- (4) Represents the amount accrued by us during the year ended December 31, 2007 in connection with the payments and reimbursements made or to be made by us to Mr. D'Urso under the separation agreement and mutual release between us and Mr. D'Urso, as described in further detail above in footnote 1 to this Summary Compensation Table and below under "Potential Payments upon Termination or Change-in-Control."
- (5) Represents the amount of matching contributions made by us to the IVAX Diagnostics, Inc. Employee Savings Plan for the benefit of the Named Executive Officer. We make matching contributions to the IVAX Diagnostics, Inc. Employee Savings Plan for the benefit of all of our participating employees, as well as all participating employees of our subsidiaries located in the United States.

### Outstanding Equity Awards at Fiscal Year-End—2007

The following table sets forth certain information regarding equity-based awards held by the Named Executive Officers as of December 31, 2007.

Name	Option Awards				
	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price	Option Expiration Date
Giorgio D'Urso .....	—	—	—	—	—
Kevin D. Clark .....	—	15,000 <sup>(1)</sup>	—	\$3.00	3/14/08
Duane M. Steele .....	—	50,000 <sup>(1)</sup>	—	\$3.00	3/14/08
	7,675	2,558 <sup>(2)</sup>	—	\$7.12	3/17/11
	10,000	—	—	\$4.35	7/13/15
Mark S. Deutsch .....	—	30,000 <sup>(1)</sup>	—	\$3.00	3/14/08
	3,837	1,279 <sup>(2)</sup>	—	\$7.12	3/17/11
	10,000	—	—	\$4.35	7/13/15

- (1) Vests the day before the expiration date; provided, however, that if the Named Executive Officer purchases on the open market a number of shares of our common stock equal to 20% of the total number of shares of our common stock underlying the option award, then the option award will fully and immediately vest; provided, however, that if the Named Executive Officer subsequently disposes of any shares of our common stock such that the number of shares of our common stock remaining is less than 20% of the total number of shares of our common stock underlying the option award, then the option award will vest the day before the expiration date.
- (2) Vests March 17, 2008.

### Potential Payments upon Termination or Change-in-Control

On October 1, 1998, the pre-merger IVAX Diagnostics entered into a five-year employment agreement with Giorgio D'Urso, our former Chief Executive Officer and President, at a base annual salary of \$348,519, with discretionary annual adjustments. We assumed this employment agreement in the merger of the pre-merger IVAX Diagnostics with b2bstores.com, Inc. We previously extended the term of Mr. D'Urso's employment agreement until February 24, 2010. Pursuant to the terms and conditions of this employment agreement, we were

permitted to terminate Mr. D'Urso's employment with or without cause at any time upon written notice. For a termination without cause, we would have been required to pay Mr. D'Urso his then current annual base salary in installments for the remainder of the employment term. This employment agreement further provided that, while employed by us and for a two-year period thereafter, Mr. D'Urso would not be permitted to employ or contract with any of our current or former employees, except former employees who have not been employed by us for more than one year.

In connection with Mr. D'Urso's resignation as our Chief Executive Officer and President, effective January 10, 2008, Mr. D'Urso's employment agreement was terminated, and we and Mr. D'Urso entered into a separation agreement and general release. Pursuant to the terms and conditions of this separation agreement and general release, we paid Mr. D'Urso a one-time lump-sum payment of \$495,000 and agreed to reimburse Mr. D'Urso for his group health insurance under COBRA until the earlier of July 10, 2008 or such time as Mr. D'Urso becomes covered under another group health plan. This separation agreement and general release also includes releases by and between us and Mr. D'Urso, as well as non-competition, non-solicitation and non-disparagement covenants by Mr. D'Urso.

*Compensation of Directors*

The Compensation Committee of the Board recommends director compensation to the Board based on factors it considers appropriate, market conditions and trends and the recommendations of management. In 2007, each of our non-employee directors received a cash retainer of \$15,000 for his service on the Board. Additionally, each member of the Audit Committee and each of our non-employee directors who served on the Compensation Committee received cash retainers of \$5,000 and \$2,500, respectively, for his service on such committees during 2007. In addition to cash compensation, each of our non-employee directors was awarded a grant of options to purchase 25,000 shares of our common stock under our 1999 Performance Equity Plan with an exercise price of \$1.00 per share, which was the closing price of our common stock on the American Stock Exchange on August 1, 2007, and which fully vested immediately upon grant. Directors who were employed by us, Teva Pharmaceutical Industries Limited or Teva North America during 2007 did not receive any compensation for their service on the Board or the committees of the Board during 2007.

**Director Compensation—2007**

The following table sets forth certain information regarding the compensation paid to our directors for their service during the fiscal year ended December 31, 2007.

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards <sup>(1)</sup>	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Mark W. Durand	—	—	—	—	—	—	—
Richard S. Egosi	—	—	—	—	—	—	—
Fernando L. Fernandez	\$22,500	—	\$17,875	—	—	—	\$40,375
Glenn L. Halpryn	\$22,500	—	\$17,875	—	—	—	\$40,375
John B. Harley, M.D.	\$17,500	—	\$17,875	—	—	\$24,000 <sup>(2)</sup>	\$59,375
Itzhak Krinsky, Ph.D.	—	—	—	—	—	—	—
Jose J. Valdes-Fauli	\$22,500	—	\$17,875	—	—	—	\$40,375

(1) Represents the dollar amount recognized for financial statement reporting purposes for the fiscal year ended December 31, 2007, in accordance with FAS 123(R), without taking into account an estimate of forfeitures related to service-based vesting, of stock option grants, including amounts from awards granted prior to 2007. Assumptions used in the calculation of these amounts are included in Note 11 to our Consolidated Financial Statements, *Shareholders' Equity*. There were no forfeitures during 2007. The table below sets

forth the aggregate number of stock options held by each of our non-employee directors who owns options to purchase shares of our common stock as of December 31, 2007:

<u>Name</u>	<u>Stock Options</u>
Fernando L. Fernandez .....	75,000
Glenn L. Halpryn .....	125,000
John B. Harley, M.D. ....	100,000
Jose J. Valdes-Fauli .....	110,000

- (2) Represents the aggregate dollar amount earned by Dr. Harley during 2007 under that certain oral consulting agreement between Dr. Harley and ImmunoVision, pursuant to which Dr. Harley is paid \$2,000 per month to provide ImmunoVision with technical guidance and business assistance on an as-needed basis.

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

### *Security Ownership of Certain Beneficial Owners and Management*

The following table indicates, as of March 26, 2008, information about the beneficial ownership of our common stock by (1) each director as of March 26, 2008, (2) each Named Executive Officer, (3) all directors and executive officers as of March 26, 2008 as a group and (4) each person who we know beneficially owns more than 5% of our common stock. All such shares were owned directly with sole voting and investment power unless otherwise indicated.

<u>Name</u>	<u>Shares (#)<sup>(1)</sup></u>	<u>Percent of Class (%)</u>
Teva Pharmaceutical Industries Limited .....	20,000,000	72.3%
IVAX Corporation c/o Teva Pharmaceuticals USA, Inc. 425 Privet Road P.O. Box 1005 Horsham, PA 19044		
Giorgio D'Urso <sup>(2)</sup> .....	324,000 <sup>(3)</sup>	1.2%
Kevin D. Clark .....	18,000	*
Duane M. Steele .....	80,233 <sup>(4)</sup>	*
Mark S. Deutsch .....	33,116 <sup>(5)</sup>	*
Fernando L. Fernandez .....	75,000 <sup>(6)</sup>	*
Glenn L. Halpryn .....	125,000 <sup>(7)</sup>	*
John B. Harley, M.D. ....	100,000 <sup>(8)</sup>	*
Jose J. Valdes-Fauli .....	110,000 <sup>(9)</sup>	*
Itzhak Krinsky, Ph.D. ....	—	—
Mark W. Durand .....	—	—
Richard S. Egosi .....	—	—
All directors and executive officers as of March 26, 2008 as a group (10 persons) .....	541,349 <sup>(10)</sup>	2.0%

\* Represents beneficial ownership of less than 1%.

- (1) For purposes of this table, beneficial ownership is computed pursuant to Rule 13d-3 under the Securities Exchange Act of 1934.
- (2) Mr. D'Urso resigned as our Chief Executive Officer and President and as a member of our Board of Directors, effective January 10, 2008, but his beneficial ownership of common stock is included in this table because he was a Named Executive Officer during 2007.
- (3) Includes 9,000 shares of common stock owned by Mr. D'Urso's wife. Mr. D'Urso disclaims beneficial ownership of the shares of common stock owned by his wife.

- (4) Includes options for 20,233 shares of common stock granted to Mr. Steele.
- (5) Includes options for 15,116 shares of common stock granted to Mr. Deutsch.
- (6) Includes options for 75,000 shares of common stock granted to Mr. Fernandez.
- (7) Includes options for 125,000 shares of common stock granted to Mr. Halpryn.
- (8) Includes options for 100,000 shares of common stock granted to Dr. Harley.
- (9) Includes options for 110,000 shares of common stock granted to Mr. Valdes-Fauli.
- (10) Does not include the 324,000 shares of common stock beneficially owned by Mr. D'Urso and his wife as a result of Mr. D'Urso's resignation as our Chief Executive Officer and President and as a member of our Board of Directors, effective January 10, 2008.

*Equity Compensation Plan Information*

The following table sets forth information, as of December 31, 2007, with respect to compensation plans under which shares of our common stock are authorized for issuance.

Plan category	Number of shares to be issued upon exercise of outstanding stock options (a)	Weighted-average exercise price of outstanding stock options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by stockholders . . . .	784,949	\$3.66	1,816,239
Equity compensation plans not approved by stockholders . . . .	<u>0</u>	<u>\$ —</u>	<u>0</u>
Total . . . . .	<u>784,949</u>	<u>\$3.66</u>	<u>1,816,239</u>

**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE**

*Majority Stockholder (Parent Company)*

Teva, indirectly through its wholly-owned IVAX subsidiary, owns approximately 72.3% of the outstanding shares of our common stock.

*Certain Relationships and Related Transactions*

Upon completion of the merger of the pre-merger IVAX Diagnostics, we entered into a registration rights agreement with IVAX. The registration rights agreement required us to file a registration statement on Form S-3 (at any time after one year, and before the earlier of five years, following the completion of the merger or such time at which all the shares of our common stock owned by IVAX can be sold in any three-month period without registration) to register not less than \$1.0 million of our common stock owned by IVAX. Additionally, IVAX was permitted to "piggyback" on registrations initiated by us or other holders exercising similar demand registration rights. The registration rights agreement expired on March 15, 2006.

In connection with the merger of the pre-merger IVAX Diagnostics, we entered into a shared services agreement with IVAX pursuant to which IVAX would continue to provide administrative and management services previously provided by IVAX to the pre-merger IVAX Diagnostics prior to the merger at IVAX' cost plus 15% for a period of three months. These services may include payroll, including printing paychecks and making associated tax filings; treasury, including cash management services such as disbursements, receipts, banking and investing; insurance, including procuring and administering policies; human resources, including administering employee benefits and plans; financial reporting, including public reports; income taxes; and information systems, including network and website hosting, phone and data systems, software licenses and information systems support.

In connection with the merger of the pre-merger IVAX Diagnostics, we entered into a use of name license agreement with IVAX that grants us a non-exclusive, royalty free license to use the name "IVAX." IVAX may terminate the license upon 90 days' written notice. Upon termination of the license agreement, we must take all steps reasonably necessary to change our name as soon as practicable. If IVAX abandons its use of the name, IVAX must transfer all rights to the name to us. The termination of this license agreement by IVAX could have a material adverse affect on us and our ability to market our products.

Prior to, and for a short time after, Teva's acquisition of IVAX, we, as a subsidiary of IVAX, had directors and officers insurance, as well as property insurance coverage, that fell within the scope of IVAX' directors and officers insurance and property insurance policies. In 2006, we purchased our own directors and officers insurance and property insurance policies and, accordingly, no longer fall within the scope of Teva's or IVAX' directors and officers insurance or property insurance policies.

Giulio D'Urso, the son of Giorgio D'Urso, our former Chief Executive Officer and President, was party to employment and consultant agreements with us and our subsidiaries, under which he received an aggregate of approximately \$164,000 annually, subject to change based on currency exchange rate fluctuations. In October 2007, we notified Giulio D'Urso of our election not to renew his consulting agreement, which is scheduled to expire in accordance with its terms in April 2008 and, in November 2007, we terminated Giulio D'Urso's employment agreement, effective immediately.

*Director Independence*

Our Board of Directors has determined that four of its members—Fernando L. Fernandez, Glenn L. Halpryn, John B. Harley, M.D., and Jose J. Valdes-Fauli—are "independent," as such term is defined in the applicable rules of the American Stock Exchange relating to the independence of directors. In determining that Dr. Harley is independent, our Board of Directors considered the oral consulting agreement between Dr. Harley and ImmunoVision, pursuant to which Dr. Harley is paid \$2,000 per month to provide ImmunoVision with technical guidance and business assistance on an as-needed basis. Our Board of Directors also considered the license agreement between us and JK Autoimmunity, Inc., a corporation of which Dr. Harley is the controlling shareholder, pursuant to which JK Autoimmunity, Inc. has granted an exclusive worldwide license to us for certain patents, rights and technology relating to monoclonal antibodies against autoimmune RNA proteins developed by Dr. Harley in exchange for specified royalty payments, including an annual minimum royalty of \$10,000 for each licensed product utilized by us.

**ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES**

The following table sets forth the aggregate fees billed to us by PricewaterhouseCoopers LLP, our principal accountant for the fiscal years ended December 31, 2007 and 2006.

	For the years ended December 31,	
	2007	2006
Audit Fees .....	\$312,500	\$330,600
Audit-Related Fees .....	68,100	—
Tax Fees .....	—	—
All Other Fees .....	7,000	—
Total Fees .....	<u>\$387,600</u>	<u>\$330,600</u>

In the table above, pursuant to their definitions under the applicable regulations of the Securities and Exchange Commission, "audit fees" are fees for professional services rendered for the audit of our annual financial statements and review of our financial statements included in our quarterly reports on Form 10-Q

and for services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements; "audit-related fees" are fees for assurance and related services that are reasonably related to the performance of the audit and review of our financial statements, and primarily include accounting consultations and audits in connection with potential acquisitions; "tax fees" are fees for tax compliance, tax advice and tax planning; and "all other fees" are fees for any services not included in the first three categories.

The Audit Committee is responsible for pre-approving all audit services and permitted non-audit services to be performed by our principal accountant, except in those instances which do not require such pre-approval pursuant to the applicable regulations of the Securities and Exchange Commission. The Audit Committee has established policies and procedures for its pre-approval of audit services and permitted non-audit services and, from time to time, the Audit Committee reviews and revises its policies and procedures for pre-approval.

## PART IV

### ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

#### (a) DOCUMENTS FILED AS PART OF THIS ANNUAL REPORT ON FORM 10-K:

##### (1) FINANCIAL STATEMENTS

The following consolidated financial statements of us and our subsidiaries are included in Part II, Item 8 of this Annual Report on Form 10-K:

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2007 and 2006

Consolidated Statements of Operations for the years ended December 31, 2007 and 2006

Consolidated Statements of Shareholders' Equity for the years ended December 31, 2007 and 2006

Consolidated Statements of Cash Flows for the years ended December 31, 2007 and 2006

Notes to Consolidated Financial Statements

##### (2) FINANCIAL STATEMENT SCHEDULES

All financial statement schedules have been omitted because the information is either not applicable or not required or because the information is included in our Consolidated Financial Statements or the related Notes to our Consolidated Financial Statements.

##### (3) EXHIBITS

The following exhibits are either filed as a part of or furnished with this Annual Report on Form 10-K or are incorporated into this Annual Report on Form 10-K by reference to documents previously filed as indicated below:

<u>Exhibit Number</u>	<u>Description</u>	<u>Method of Filing</u>
3.1	Amended and Restated Certificate of Incorporation	Incorporated by reference to our Schedule 14A filed on June 25, 2002.
3.2	Amended and Restated Bylaws, as Amended	Filed herewith.
4.1	Specimen Common Stock Certificate	Incorporated by reference to our Form 10-K filed on April 1, 2002.
10.1	Form of Indemnification Agreement between IVAX Diagnostics, Inc. and each of its directors	Incorporated by reference to our Form 10-K filed on March 31, 2003.

<u>Exhibit Number</u>	<u>Description</u>	<u>Method of Filing</u>
10.2	Use of Name License Agreement, dated March 14, 2001, between IVAX Diagnostics, Inc. and IVAX Corporation	Incorporated by reference to our Form 10-K filed on April 1, 2002.
10.3	Shared Services Agreement, dated March 14, 2001, between IVAX Diagnostics, Inc. and IVAX Corporation	Incorporated by reference to our Form 10-K filed on April 1, 2002.
10.4*	Separation Agreement and General Release, dated as of January 3, 2008, by and between IVAX Diagnostics, Inc. and Giorgio D'Urso	Incorporated by reference to our Form 8-K filed on January 3, 2008.
10.5	1999 Performance Equity Plan	Incorporated by reference to our Form SB-2 filed on October 6, 1999.
10.6	1999 Stock Option Plan	Incorporated by reference to our Form 10-K filed on April 1, 2002.
10.7	Form of Nonqualified Stock Option Agreement (Employee)	Incorporated by reference to our Form 10-K filed on March 31, 2005.
10.8	Form of Nonqualified Stock Option Agreement (Non-Employee Director)	Incorporated by reference to our Form 10-K filed on March 31, 2005.
21.1	Subsidiaries of IVAX Diagnostics, Inc.	Filed herewith.
23.1	Consent of Independent Registered Public Accounting Firm—PricewaterhouseCoopers LLP	Filed herewith.
31.1	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith.
31.2	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith.
32.1	Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	**
32.2	Certification of Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	**

\* This exhibit is a management contract or compensatory plan or arrangement which is required to be filed with this Annual Report on Form 10-K by Item 601 of Regulation S-K.

\*\* Pursuant to Item 601(b)(32) of Regulation S-K, this exhibit is furnished, rather than filed, with this Annual Report on Form 10-K.



We have made forward-looking statements, which are subject to risks and uncertainties, in this annual report. Forward-looking statements may be preceded by, followed by or otherwise include the words “may,” “will,” “believes,” “expects,” “anticipates,” “intends,” “plans,” “estimates,” “projects,” “could,” “would,” “should” or similar expressions or statements that certain events or conditions may occur. Actual results, performance or achievements could differ materially from those contemplated, expressed or implied by these forward-looking statements. These forward-looking statements are based largely on our expectations and the beliefs and assumptions of our management and on the information currently available to it and are subject to a number of risks and uncertainties, including, but not limited to: risks and uncertainties associated with our implementation of our change in strategic direction to focus on the development of the Mago® 4 as a platform for marketing our kits and to place any further development of the PARSEC® System on hold indefinitely, including, without limitation, that we may not successfully implement the change in strategic direction, that we may not achieve improved cash flow or increased stockholders’ value as a result of our implementation of the change in strategic direction and that the implementation of the change in strategic direction will not successfully position us to focus on our core business or to attempt to achieve profitability when expected or at all; risks and uncertainties regarding the Mago® 4, including, without limitation, that the Mago® 4 may not perform as or be available when expected or at all, that we may not be able to obtain all necessary regulatory approvals for the Mago® 4 when expected or at all, that we may not broaden our product portfolio of diagnostic assays or continue to deliver to our customers the technological innovation that they expect from us as a result of our focus on the development of the Mago® 4, that we may not be successful in our marketing of the Mago® 4, that customers may not integrate the Mago® 4 into their operations as readily as expected, and that sales and reagent rentals of the Mago® 4 may adversely affect sales and reagent rentals of the Mago® Plus; risks and uncertainties associated with the PARSEC® System, including, without limitation, that the PARSEC® System may not ever be available and that our international activities associated with the PARSEC® System will be adversely impacted by the change in strategic direction described above; the risk that our efforts to contain expenses may not result in further reductions in operating expenses; the risk that we may not achieve revenue growth; the risk that we may not achieve improved financial performance on a sustained and continuous basis or at all; the risk that we will not successfully build upon our core business and strengthen our position; the risk that we may not successfully develop additional strategic business and scientific relationships and, in the event we develop additional strategic business and scientific relationships, the risk that any such relationships may not be successful or otherwise result in our improved financial performance; and other economic, competitive, governmental, technological and other risks and factors discussed elsewhere in our periodic filings with the Securities and Exchange Commission, including, without limitation, in the section entitled “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2007 which has been provided as a portion of this annual report. Many of these risks and factors are beyond our control.

# **IVAX**

***Diagnostics, Inc.***

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