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# ***IVAX*** ***Diagnostics, Inc.***

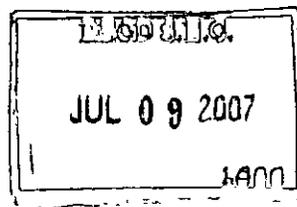
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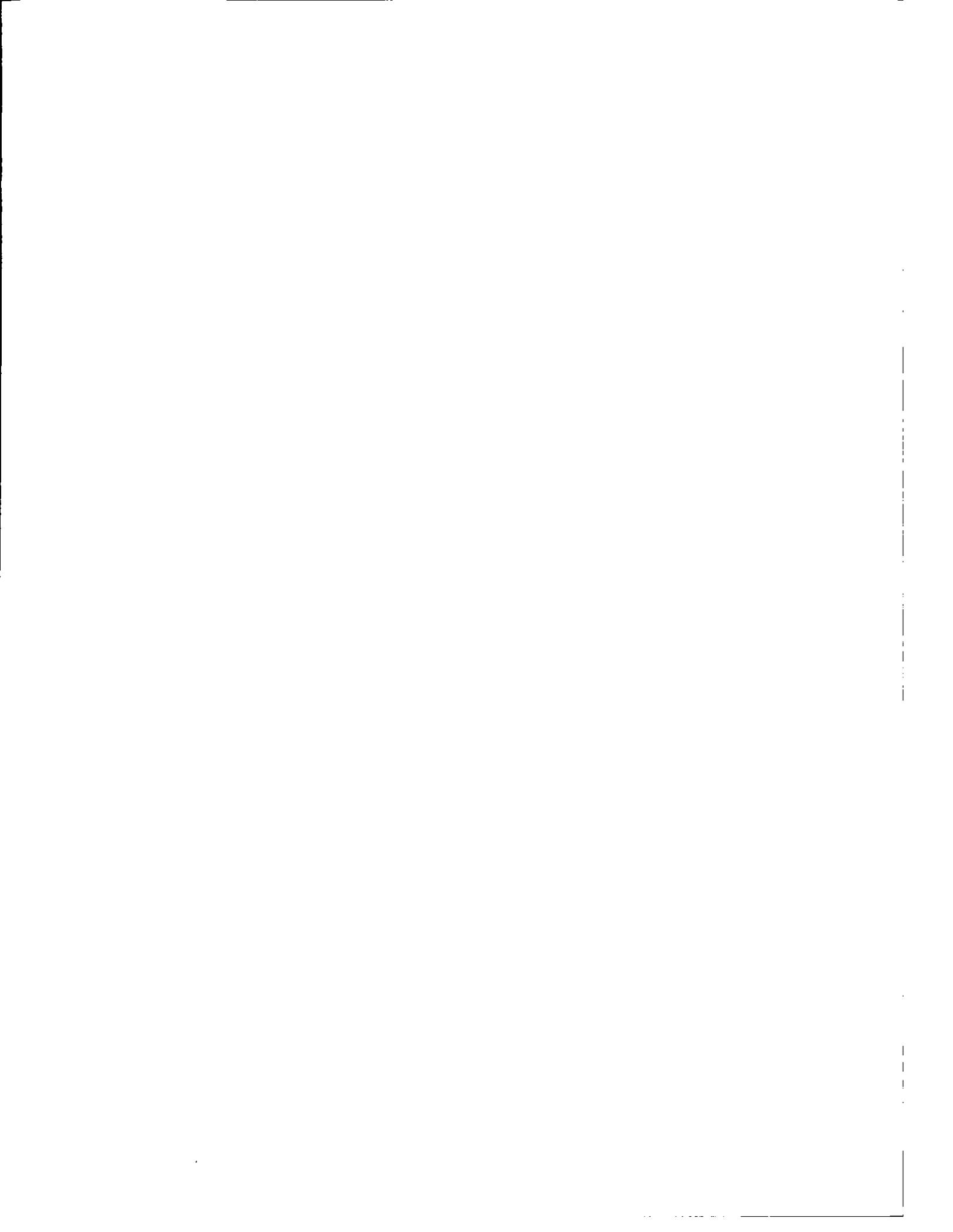
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## **2006 Annual Report**



June 29, 2007

## **To Our Stockholders**

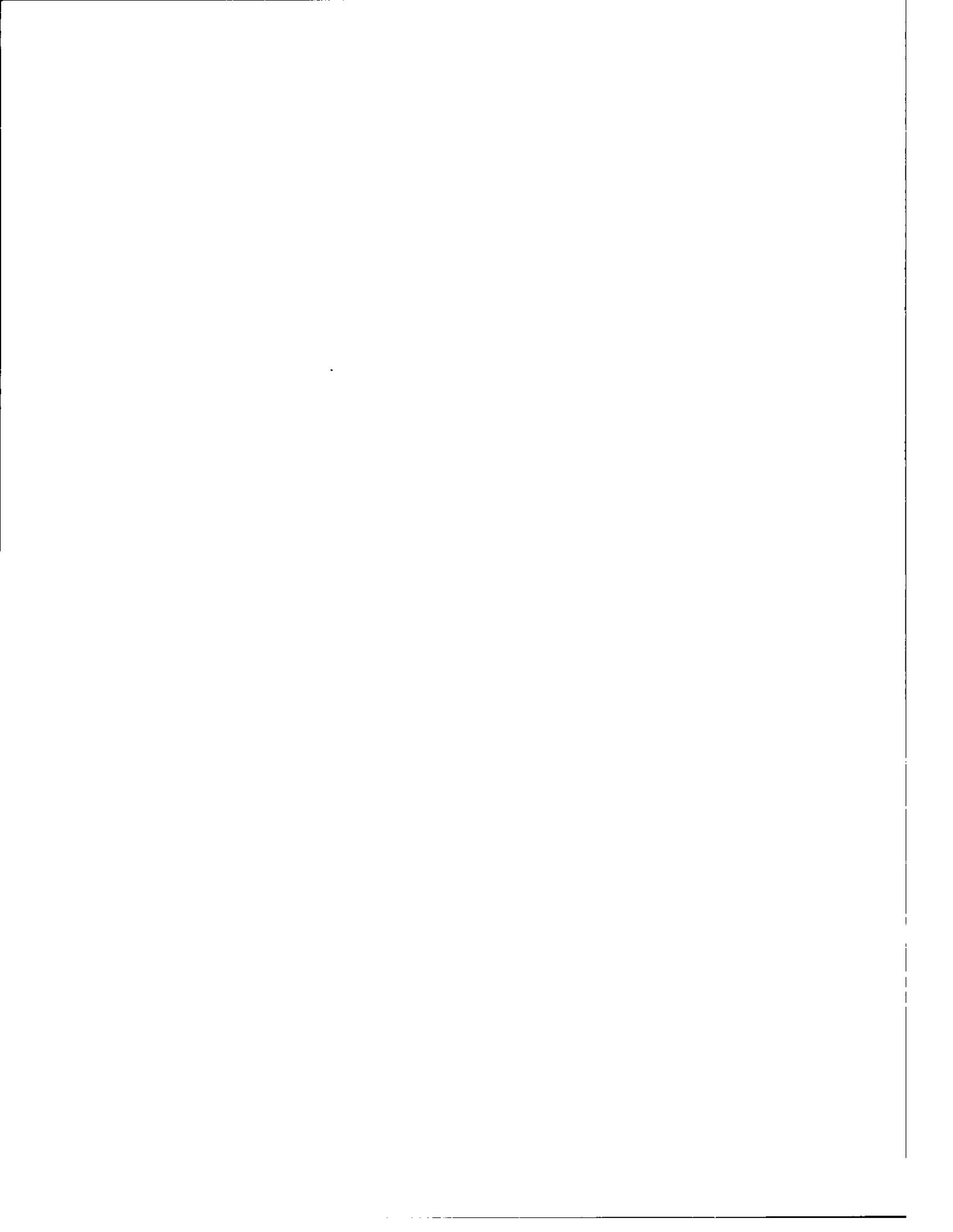
2006 was a challenging year for IVAX Diagnostics, Inc. and I appreciate the opportunity to provide you with a summary of the financial highlights and important events.

For the full year 2006, revenues decreased 1.2% to \$19,523,000 from \$19,762,000 for the full year 2005. For the full year 2006, our net loss was \$2,809,000, compared to net loss of \$510,000 for the full year 2005. As previously announced, our net loss for 2006 increased significantly as a result of increases in operating expenses compared to 2005, primarily in general and administrative expenses and research and development expenses. The increase in general and administrative expenses compared to 2005 was primarily the result of the approximately \$1.7 million reduction in general and administrative expenses that had occurred in 2005 when we recorded a bad debt recovery and reduced our allowance for doubtful accounts to recognize the impact of previously outstanding Italian accounts receivable. The increase in research and development expenses was primarily associated with our PARSEC® System, which remains our top priority. Although our results for 2006 were disappointing, we remain optimistic about our new instrumentation initiatives.

Our principal new product is the PARSEC® System, our new proprietary automated testing system. We previously indicated that we expected to submit our 510(k) application for the PARSEC® System to the Food and Drug Administration during the second quarter of 2007. However, we now believe that this target will not be realized and that our 510(k) submission to the Food and Drug Administration will occur during the third quarter of 2007. We have also announced that we are upgrading our existing Mago® Plus instrument to a new version that will be called the Mago® 4. This enhanced Mago® instrument is expected to be able to perform both ELISA and IFA techniques simultaneously, perform positive sample identification, and utilize disposable pipette tips. We expect to submit a separate 510(k) application to the Food and Drug Administration for this new instrument and will make an announcement once this application has been submitted. Both of these new instrument systems are expected to be able to be used in conjunction with the new hepatitis kits that we intend to begin manufacturing at our Italian facilities during the fourth quarter of this year.



Giorgio D'Urso,  
President and Chief Executive 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, 2006  
Commission File Number 1-14798

**IVAX Diagnostics, Inc.**  
(Exact name of registrant as specified in its charter)

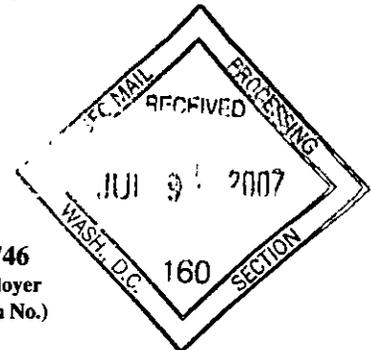
Delaware  
(State or other jurisdiction of  
incorporation or organization)

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, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer  Accelerated filer  Non-accelerated filer

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, 2006, was approximately \$14,206,000, 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, 2007, there were 27,649,887 shares of common stock outstanding.

**Documents Incorporated by Reference:**

Portions of the registrant's Proxy Statement relating to the registrant's 2007 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K.

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**IVAX Diagnostics, Inc.**  
**Annual Report on Form 10-K**  
**for the year ended December 31, 2006**

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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 new version of the Mago<sup>®</sup> Plus outside of the United States. We have designed our new proprietary instrument system, named the PARSEC<sup>®</sup> System, in a modular format, which we believe should permit different detection technologies to be incorporated. We expect that this design should enable customers to utilize not only ELISA-based kits, but also other methods such as IFA and chemiluminescent-based assays in the future. We also believe that the PARSEC<sup>®</sup> System's design is scalable, which we believe should give customers the ability to "customize" the configuration of the PARSEC<sup>®</sup> System to the testing and work flow requirements of their particular laboratories. We have not yet received final regulatory approval for the PARSEC<sup>®</sup> System, nor is it yet available for commercial release in the United States. 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 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 11 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 develops and manufactures scientific and laboratory instruments, including its proprietary Mago<sup>®</sup> Plus and Aptus<sup>®</sup> systems, which include hardware, reagents, and software. The Mago<sup>®</sup> Plus and Aptus<sup>®</sup> systems, in association with over 100 specific 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 90% of Delta's customers in Italy are government owned hospitals and the remaining 10% are 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 46 assays that the United States Food and Drug Administration, or 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., then a wholly-owned subsidiary of IVAX 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 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 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, our approximately 72.3% stockholder, 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 \$27.7 billion in 2003 and estimated to grow at a rate of 7% annually. Of this total \$27.7 billion market, the world immunoassay market in which we operate is estimated by industry analysts to be \$5.37 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 includes 26 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<sup>®</sup> Plus and Aptus<sup>®</sup> systems and PARSEC<sup>®</sup> System 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. While some of our competitors offer proprietary instruments, other competitors use third parties to manufacture these instruments for them. We believe that the cost advantage we enjoy from our own manufacture of the Mago<sup>®</sup> Plus and Aptus<sup>®</sup> systems and the PARSEC<sup>®</sup> System, 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. We expect that our new proprietary PARSEC<sup>®</sup> System should enable us to expand the menu of test kits that we currently offer and that we should be able to expand into testing sectors beyond the autoimmune and infectious disease products. We expect that the PARSEC<sup>®</sup> System will be marketed to hospitals, reference testing laboratories and clinics as well as pharmaceutical and biotechnology research companies. We presented the PARSEC<sup>®</sup> System at the American Association for Clinical Chemistry (AACC) Clinical Lab Exposition in Chicago, Illinois in July 2006 and the Medica Exhibition in Dusseldorf, Germany in November 2006. We plan to submit a 510(k) application to the FDA for the PARSEC<sup>®</sup> System. As a result, commercial deliveries of the PARSEC<sup>®</sup> System in the United States will await regulatory clearance of the 510(k). Commercial activities outside of the United States are not expected to be impacted by this process, and deliveries to customers abroad will continue to be made on a select basis.

*Research and Development.* We devote substantial resources for research and development. For the years ended December 31, 2006, 2005 and 2004, we incurred \$2.4 million, \$1.8 million and \$1.3 million, respectively, for research and development activities.

Our research and development efforts are targeted primarily towards the development of our new proprietary PARSEC<sup>®</sup> System. 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.

*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.

On May 15, 2002, we consummated the acquisition of certain of the assets of the global enzyme immunoassay product line of Sigma Diagnostics. As a result of the consummation of the transaction with Sigma Diagnostics, we no longer sell reagents or instrumentation to Sigma Diagnostics, which had been our largest customer during 2001 and 2000 and which had marketed such reagents and instrumentation throughout the world under previous agreements with us. Instead, we sell enzyme immunoassay instrumentation and reagents directly to Sigma Diagnostics' former customer base.

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, 2006, we had approximately 120 full time employees, of whom 16 were managerial, 47 were technical and manufacturing, 13 were administrative, and 42 were sales and marketing.

*Intellectual Property.* The technology associated with the design and manufacture of the Mago® Plus and Aptus® instruments is not protected by patent registrations or license restrictions. The Mago® Plus instrument has been our primary product. In the future, we expect that the PARSEC® System will become our primary product. We have filed several patent applications related to the new innovative features in the PARSEC® System.

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 the agreement, we are required to take all steps reasonably necessary to change our name as soon as is practicable. The termination of this agreement 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. Diamedix is listed as a registered establishment with the FDA and Delta has received UNI ISO 9001 certification complemented by the requirements of UNI CEI EN ISO 13485 validating its quality system. 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 may or may not be subject to pre-market notification. 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 performance standards, and are usually subject to pre-market notification. Usually, Class III devices are those that must receive Pre-Market Approval by the FDA to ensure their safety and effectiveness. Most of our products are classified as Class I or II devices. Generally, before a new test kit can be introduced to the market, it is necessary to obtain FDA clearance in the form of a pre-market 510(k) notification. A 510(k) notification provides data to show that the new device is substantially equivalent to other devices that were introduced into the marketplace prior to May 1976, or pre-amendment devices. Almost all of the products sold by us have received 510(k) clearance. In addition, customers using diagnostic tests for clinical purposes in the United States are also 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.

Additionally, the products we sell are subject to extensive regulation by governmental authorities in the United States and other countries, including, among other things, the regulation of the testing, approval, manufacturing, 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 Conformance 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 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. We have also received an ISO 13485:2003 certificate, 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 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 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 our new proprietary instrument system and the expansion of our test kit menu, 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 have developed a new proprietary instrument system, named the PARSEC® System. While deliveries of the PARSEC® System to customer laboratories abroad have already begun on a select basis, we intend to seek 510(k) clearance from the FDA for the PARSEC® System in the United States. Accordingly, commercial deliveries of the PARSEC® System in the United States will await regulatory clearance of the 510(k). There can be no assurance that we will be able to obtain 510(k) clearance from the FDA for the

PARSEC® System when anticipated or at all. Furthermore, there can be no assurance that our international activities associated with the PARSEC® System will not be impacted by the delay in the full commercial launch of the PARSEC® System in the United States. 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, goodwill and product intangibles will not be impacted by the delay in the full commercial release of the PARSEC® System.

We expect that the PARSEC® System will become our primary product and will 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. However, the development and marketing of new or enhanced products is a complex and uncertain process. Accordingly, we cannot be certain that:

- the PARSEC® System will be available when or perform as expected,
- the PARSEC® System will become our primary product,
- the PARSEC® System will enable us to expand the menu of test kits we offer,
- the PARSEC® System will be a source of revenue growth for us,
- we will receive financial benefits or achieve improved operating results after the full commercial release of the PARSEC® System,
- we will be successful in the marketing of the PARSEC® System, or
- customers will integrate the PARSEC® System into their operations as readily as expected.

Additionally, in an effort to expand the test kit menu 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.

Any of the above factors may 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.

**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, as well as our new proprietary PARSEC® System, 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 2006, we incurred approximately \$2.4 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. We have filed several patent applications related to the new innovative features in the PARSEC® System. However, we cannot be sure that we will receive patents for any of these patent applications or that any patents that we receive will provide competitive advantages for the PARSEC® System. We also cannot be sure that competitors will not challenge, invalidate or void the application of these patents. In addition, patent rights may not prevent our competitors from developing, using or selling products that are similar or functionally equivalent to our products.

The technology associated with the design and manufacture of the Mago® Plus 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.

**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 testing, approval, manufacturing, 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, 2006, we recorded net revenues of \$19.5 million and net loss of \$2.8 million. For the year ended December 31, 2005, we recorded net revenues of \$19.8 million and net loss of \$0.5 million. For the year ended December 31, 2004, we recorded net revenues of \$18.9 million and net income

of \$0.2 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.

**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, 2006 and 2005, our accounts receivable were \$8.6 million and \$7.7 million, respectively, and our allowance for doubtful accounts was \$1.1 million and \$1.0 million, respectively. As of December 31, 2006 and 2005, \$6.2 million and \$5.3 million, respectively, of our accounts receivable were due in Italy, and \$0.7 million and \$0.7 million, respectively, of our allowance for doubtful accounts related to Italian accounts receivable. Approximately 90% of Delta's customers in Italy are government owned hospitals and the remaining 10% are private laboratories. As of December 31, 2006 and 2005, 66.2% and 57.0%, 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.

**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, 2006, 2005 and 2004, Delta represented 33.1%, 34.7% and 36.0%, 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, 2006, 2005 and 2004, 33.1%, 34.7% and 36.0% of our net revenue, respectively, 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.

**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, 2006 and 2005, our total inventories included approximately \$1.3 million and \$1.0 million, respectively, in PARSEC® System 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 future design changes to, or the development of improved instrument versions of, the PARSEC® System or as a result of future demand for the PARSEC® System, 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. The production of pre-launch inventories for our products, including, without limitation, the PARSEC® System, 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, if at all, or that we may not be able to find alternative uses for such inventory. As of December 31, 2006 and 2005, our total inventories included approximately \$1.3 million and \$1.0 million, respectively, in PARSEC® System instrumentation and instrument components. If any of these events were to occur or the launch of the products is significantly postponed, 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.

**There are inherent uncertainties involved in estimates, judgments and assumptions used in the preparation of financial statements in accordance with United States 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 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,
- 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.

**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. 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.

Under the current and proposed rules and regulations of the Securities and Exchange Commission, we are currently not required to comply with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 until we file our Annual Report on Form 10-K for our fiscal year ending December 31, 2007, so long as we continue to meet the definition of a non-accelerated filer. In our Annual Report on Form 10-K for the year ending December 31, 2007, our management will be required to provide an assessment as to the effectiveness of our internal control over financial reporting, which assessment will be deemed furnished to rather than filed with the Securities and Exchange Commission. 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 assessment and attestation 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 and that our management will be able to certify as to the effectiveness of our internal control over financial reporting, there is no assurance that we will do so. If we are unable to timely comply with Section 404, our management is unable to certify as to the effectiveness of our internal control over financial reporting or our independent registered public accounting firm is unable to attest to that certification, the price of our common stock may be adversely affected. Even if we timely meet the certification and attestation 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 national securities brokerage firm. 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, three members of our board of directors are employees 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. Additionally, our financial results will be included in Teva's consolidated financial statements for so long as Teva continues to own at least 50% of our common stock. Our directors who may hold positions with Teva, and who may also be holders of Teva ADRs, may therefore consider not only the short-term and long-term impact of financial and operating decisions on us, but also the impact of these decisions on Teva's consolidated financial results and stockholders. 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 the agreement, we are required to take all steps reasonably necessary to change our name as soon as practicable. The termination of this 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 only 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 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. These statements are based on the beliefs and assumptions of our management and on the information currently available to it. 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 commercial release of our new proprietary instrument system, named the PARSEC® System;
- our ability to receive regulatory approval for the PARSEC® System when expected, or at all;
- the ability of the PARSEC® System to be available when or to perform as expected;
- the impact of the delay in the full commercial release of the PARSEC® System on the judgments and estimates we have made with respect to our inventory, goodwill and product intangibles and on our financial condition, operating results and cash flows;
- the impact of the delay in the full commercial launch of the PARSEC® System in the United States on our international activities associated with the PARSEC® System and on our financial condition and operating results;

- the impact on our financial condition and operating results of making or changing judgments and estimates regarding our inventory as a result of future design changes to, or the development of improved instrument versions of, the PARSEC® System or as a result of future demand for the PARSEC® System;
- the ability of the PARSEC® System to be a source of revenue growth for us;
- our ability to receive financial benefits or achieve improved operating results after the full commercial release of the PARSEC® System;
- the ability of the PARSEC® System to be a factor in our growth;
- the ability of the PARSEC® System to expand the menu of test kits we offer;
- making the PARSEC® System our primary product;
- our ability to market the PARSEC® System;
- our customers' integration of the PARSEC® System 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 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 internally manufacture our own hepatitis products and raw materials for these products, to obtain regulatory approval for these products and to become competitive in markets outside of the United States;
- 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 effects of utilizing cash to assist our subsidiary Delta Biologicals in maintaining its compliance with capital requirements established by Italian law;
- 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, when required, 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, 2006.

## 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."

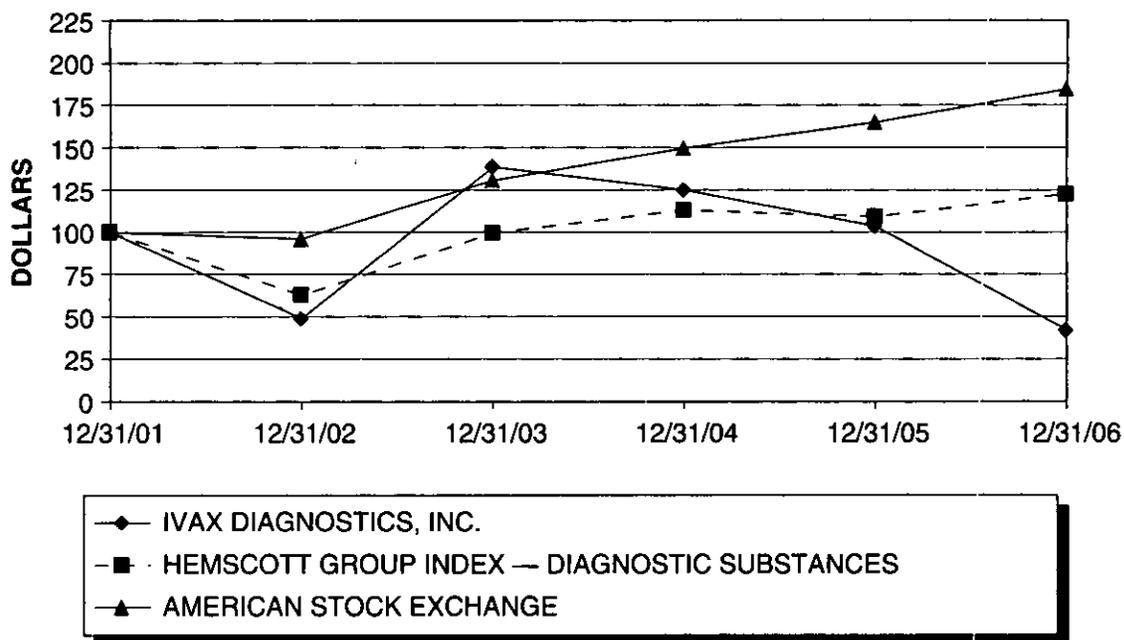
As of the close of business on March 26, 2007, there were approximately 47 holders of record of our common stock.

The following table sets forth the high and low sales prices of a share of our common stock for each quarter in 2006 and 2005, as reported by the American Stock Exchange:

	<u>High</u>	<u>Low</u>
<b>2006</b>		
Fourth Quarter .....	\$1.70	\$1.20
Third Quarter .....	2.08	1.25
Second Quarter .....	3.30	1.61
First Quarter .....	3.80	3.15
<b>2005</b>		
Fourth Quarter .....	\$4.26	\$3.01
Third Quarter .....	4.70	3.50
Second Quarter .....	4.99	3.51
First Quarter .....	4.36	3.13

We did not declare or pay cash dividends on our common stock during 2006 or 2005 and we do not intend to pay any cash dividends in the foreseeable future.

Set forth below are a graph and a table comparing the cumulative total returns (assuming reinvestment of dividends) for our common stock, the Hemscott Group Index—Diagnostic Substances and the American Stock Exchange. The graph and the table show annual comparisons, assuming \$100 was invested on December 31, 2001.



	<u>12/31/01</u>	<u>12/31/02</u>	<u>12/31/03</u>	<u>12/31/04</u>	<u>12/31/05</u>	<u>12/31/06</u>
IVAX Diagnostics, Inc. ....	100.00	48.85	138.79	125.00	103.45	41.95
Hemscott Group Index—Diagnostic Substances .....	100.00	62.58	99.46	112.94	109.05	122.53
American Stock Exchange .....	100.00	96.01	130.68	149.65	165.03	184.77

## ITEM 6. SELECTED FINANCIAL DATA

The following table sets forth selected historical financial data as of and for the fiscal years ended December 31, 2006, 2005, 2004, 2003 and 2002 that has been derived from, and is qualified by reference to, our Consolidated Financial Statements. The information set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operation" and the Consolidated Financial Statements and related Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

	For the Years Ended December 31,				
	2006	2005	2004	2003	2002
	(In thousands except per share data)				
<b>Consolidated Statement of Operations Data:</b>					
Net revenue	\$19,523	\$19,762	\$18,933	\$17,673	\$13,841
Income (loss) from operations	\$(2,874)	\$ 277	\$(314)	\$(1,031)	\$(3,498)
Cumulative effect of change in accounting principle	\$ (201)	\$ —	\$ —	\$ —	\$ —
Net income (loss)	\$(2,809)	\$(510)	\$ 152	\$(675)	\$(2,830)
Cumulative effect of change in accounting principle					
per basic and diluted common share	\$ (.01)	\$ —	\$ —	\$ —	\$ —
Net income (loss) per basic and diluted common share	\$ (.10)	\$ (.02)	\$ .01	\$ (.02)	\$ (.10)
Weighted average number of shares outstanding					
Basic	27,639	27,295	27,341	27,590	28,488
Diluted	27,639	27,295	28,543	27,590	28,488
	As of December 31,				
	2006	2005	2004	2003	2002
	(In thousands)				
<b>Balance Sheet Data:</b>					
Working capital	\$18,365	\$20,036	\$22,993	\$24,334	\$23,521
Total assets	\$33,707	\$35,904	\$36,914	\$38,365	\$37,423
Total liabilities	\$ 5,969	\$ 5,714	\$ 4,868	\$ 4,402	\$ 4,027
Total stockholders' equity	\$27,738	\$30,190	\$32,046	\$33,963	\$33,396

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

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 45 to 64 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 our subsidiaries located in the United States and corporate operations. Our other segment—the Italian region—contains our subsidiary located in Italy.

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 100 specific 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 90% of Delta's customers in Italy are government owned hospitals and the remaining 10% are 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.

Diamedix' products are sold in the United States through Diamedix' sales force. Diamedix markets 46 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.

### **Majority Stockholder**

On July 25, 2005, IVAX, our approximately 72.3% stockholder, 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, 2006 Compared To The Year Ended December 31, 2005***

##### *Overview*

Net losses totaled \$2,809,000 in 2006 and \$510,000 in 2005. Operating loss was \$2,874,000 in 2006 compared to operating income of \$277,000 in 2005. Net income and income from operations significantly decreased in 2006 compared to 2005 due to an increase in operating expenses of \$2,548,000, primarily in general and administrative expenses and research and development expenses. The increase in general and administrative expenses of \$2,133,000 was caused primarily by the 2005 bad debt recovery of \$1,690,000 recorded when we reduced our allowance for doubtful accounts to recognize the impact of the May 2005 collection of previously outstanding Italian accounts receivable from hospitals located in a particular region in Italy. Partially offsetting this reduction in general and administrative expenses was a \$580,000 charge for compensation expense and related payroll taxes in 2005 recorded as a result of our cancellation of 499,398 options to purchase shares of our common stock, which were granted under our 1999 Stock Option Plan, in exchange for a payment to participating option holders pursuant to the July 2005 program that we had offered. Also contributing to the increase in operating expenses was an increase in research and development expenses, caused primarily by a \$509,000 write-off of assets related to the PARSEC® System. These operating expense increases were partially offset by a reduction in selling expenses. Revenue decreased \$239,000 to \$19,523,000 in 2006, and cost of sales increased \$364,000 to \$8,457,000 in 2006, resulting in a gross profit decrease of \$603,000 to \$11,066,000 in

2006. The decline in revenue was due to lower Italian revenue, which was principally caused by a decrease in the volume of instrument sales. The decline in Italian revenue was partially offset by an increase in domestic external net revenues in 2006, primarily due to volume increases in sales made under a supply agreement to another company selling diagnostic reagent products, partially offset by lower net revenues from international sales. The gross profit decline of \$603,000, or 5.2%, from the prior year was primarily attributable to the decrease in gross margin percentage as well as to the decrease in net revenues. Gross profit as a percentage of net revenues declined to 56.7% in 2006 from 59.0% in 2005, primarily due to a reduction in gross profit percentage of Italian reagent sales due to both an increase in product cost and a decline in sales prices. Our tax provisions were \$153,000 in 2006 and \$1,077,000 in 2005, with the decrease primarily due to the recognition of deferred taxes in 2005 related to the impact of the collection of previously outstanding Italian accounts receivable and the creation of a valuation allowance to fully reserve the remaining foreign net deferred tax assets.

*Net Revenues and Gross Profit*

	<u>2006</u>	<u>2005</u>	<u>Period over Period Increase (Decrease)</u>
Net Revenues Excluding Intercompany Sales			
Domestic .....	\$13,065,000	\$12,897,000	\$ 168,000
Italian .....	6,458,000	6,865,000	(407,000)
Total .....	<u>19,523,000</u>	<u>19,762,000</u>	(239,000)
Cost of Sales .....	8,457,000	8,093,000	364,000
Gross Profit .....	<u>\$11,066,000</u>	<u>\$11,669,000</u>	<u>\$(603,000)</u>
% of Total Net Revenues .....	56.7%	59.0%	

Net revenues in 2006 decreased \$239,000, or 1.2%, from 2005. This decrease was comprised of an increase in external net revenues of \$168,000 from domestic operations offset by a decrease in external net revenue of \$407,000 from Italian operations. Domestic external net revenues in 2006 increased by 1.3% from 2005, primarily due to volume increases in sales made under a supply agreement to another company selling diagnostic reagent products, partially offset by lower net revenues from international sales. The decline in external net revenues from Italian operations includes the effect of an increase in revenue of \$68,000 due to currency fluctuations of the United States dollar relative to the Euro as further discussed in "Currency Fluctuations" below. This decrease in Italian external net revenues was primarily due to a lower volume of instrument sales and, to a lesser degree, sales price declines in response to the accelerating trend of competitive pricing pressure occurring in Italy as well as decreases in the volume of sales in the infectious disease reagent kits product line. Gross profit in 2006 decreased \$603,000, or 5.2%, from the prior year primarily as a result of the decrease in gross margin percentage as well as the decrease in net revenues. Gross profit as a percentage of net revenues declined to 56.7% in 2006 from 59.0% in 2005, primarily due to a reduction in gross profit percentage of Italian reagent sales due to both an increase in product cost and a decline in sales prices. Domestic gross margins decreased slightly due primarily to lower gross profit percentages on sales made under the supply agreement mentioned above and an increase in labor costs incurred in an effort to improve our domestic production and quality operations, partially offset by a reduction in professional fees because professional fees had been incurred in 2005 in an effort to improve our domestic production and quality operations, as well as a decrease in expenses related to the amortization of equipment on lease.

*Operating Expenses*

	<u>2006</u>	<u>% of Revenue</u>	<u>2005</u>	<u>% of Revenue</u>	<u>Period over Period Increase (Decrease)</u>
Selling Expenses					
Domestic .....	\$ 3,609,000	18.5%	\$ 3,621,000	18.3%	\$ (12,000)
Italian .....	2,275,000	11.7%	2,486,000	12.5%	(211,000)
Total .....	<u>5,884,000</u>	<u>30.1%</u>	<u>6,107,000</u>	<u>30.9%</u>	(223,000)
General and Administrative .....	5,652,000	29.0%	3,519,000	17.8%	2,133,000
Research and Development .....	2,404,000	12.3%	1,766,000	8.9%	638,000
Total Operating Expenses .....	<u>\$13,940,000</u>	<u>71.4%</u>	<u>\$11,392,000</u>	<u>57.6%</u>	<u>\$2,548,000</u>

The most significant variation in operating expenses occurred in general and administrative expenses, which increased by \$2,133,000 primarily as a result of bad debt expenses of \$223,000 in 2006 compared to bad debt recoveries of \$1,833,000 in 2005, principally resulting from the first quarter 2005 bad debt recovery of Italian accounts receivable which resulted from the receipt of previously outstanding accounts receivable balances from hospitals located within a particular region in Italy. A significant portion of this approximately 2,000,000 Euro payment related to accounts receivable against which we had previously established allowances. As a result, we recognized a \$1,690,000 bad debt recovery, which is included in general and administrative expenses, as we reduced our allowance for doubtful accounts to recognize the impact of this collection of these receivables in 2005. Partially offsetting this reduction in general and administrative expenses was approximately \$580,000 in domestic compensation expense and related payroll taxes in 2005 recorded as a result of our cancellation of 499,398 options to purchase shares of our common stock, which were granted under our 1999 Stock Option Plan, in exchange for a payment to participating option holders pursuant to the July 2005 program that we had offered, as further described in "Liquidity and Capital Resources" below. Exclusive of the effect of these 2005 transactions, general and administrative expenses increased primarily due to increases in board of director costs and legal and accounting fees necessary for public company regulatory compliance and acquisition investigation related costs. Although, in the ordinary course of our business, we evaluate potential business acquisition opportunities, we may not be successful in finding or consummating any acquisitions. Research and development expenses increased \$638,000 due to an increase in Italian research and development expenses to \$1,665,000 in 2006 from \$888,000 in 2005, partially offset by a decrease in domestic research and development expenses to \$739,000 in 2006 from \$878,000 in 2005. The increase in Italian research and development expenses was principally due to a third quarter of 2006 write-off of \$509,000 of certain assets relating to the PARSEC® System. When we determined that certain of these assets were not compatible with future instrument versions, we recorded \$355,000 of this amount within research and development expenses, consisting of \$278,000 in assets associated with PARSEC® System development and \$77,000 in inventory. As part of this analysis we became aware of, and included in this adjustment in research and development expenses, errors in prior periods totaling \$134,000, principally related to still usable fixed assets relating to the PARSEC® System that had not been properly depreciated. Other increases in Italian research and development expenses were principally due to increased payroll costs incurred as the result of the transfer to us of the technology expected to enable us to manufacture certain hepatitis products, as well as other expenditures associated with the transfer of the hepatitis technology. Domestic research and development expenses decreased in 2006 compared to 2005 principally due to a decrease in consulting expenses related to the development of the PARSEC® System. The future level of research and development expenditures 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. Partially offsetting these increases in operating expenses was a decrease of \$223,000 in selling expenses in 2006 compared to 2005, principally due to a reduction in Italian selling expenses of \$211,000 primarily as a result of lower Italian payroll related costs due to a reduction in the number of employees and agents employed by our Italian operations.

#### *Income (Loss) from Operations*

Loss from operations was \$2,874,000 in 2006 compared to income from operations of \$277,000 in 2005. Loss from operations in 2006 was composed of a loss from Italian operations of \$2,087,000, which includes the write-off of \$509,000 of certain assets relating to the PARSEC® System and a loss from domestic operations of \$824,000. Income from operations in 2005 was composed of income from Italian operations of \$971,000, which includes the effect of the bad debt recovery of Italian accounts receivable, offset by a loss from domestic operations of \$686,000, which includes the effect of the compensation expense relating to our cancellation of stock options pursuant to our July 2005 program.

#### *Other Income, Net*

Interest income increased to \$464,000 in 2006 from \$352,000 in 2005 primarily due to higher interest rates. Other expense, net totaled \$44,000 during 2006, compared to other expense, net of \$62,000 in 2005. Amounts included in

other expense, net in 2006 and 2005 were primarily net foreign currency gains and losses on transactions, particularly by our Italian subsidiary, which were denominated in currencies other than its functional currency.

#### *Income Tax Provision*

During 2006 and 2005, we recorded income tax provisions of \$153,000 and \$1,077,000, respectively. The current tax provision in 2006 relates to Italian local income taxes based upon applicable statutory rates effective in Italy while the deferred tax provision in 2006 relates to domestic tax deductible goodwill. The tax provision in 2005 is primarily composed of deferred taxes related to the allowance for doubtful accounts that was reduced in the first quarter of 2005 as a result of the collection of certain previously reserved Italian accounts receivable and the creation of a valuation allowance to fully reserve the remaining foreign deferred tax asset. No current domestic tax provision or benefit was recorded in 2006 or 2005 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 SFAS 123(R). 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 has been reduced to \$23,000, and the fair value adjustment of \$178,000 has been reported as a reduction of general and administrative expenses. A cumulative effect of a change in accounting principle was not recorded during 2005.

#### *Net Loss*

We generated net losses of \$2,809,000 in 2006 and \$510,000 in 2005. Our net losses per basic and diluted common share were \$(0.10) in 2006 and \$(0.02) in 2005. The net losses in 2006 and 2005 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, regarding the calculation of loss per share and our application of SAB 108 using the cumulative effect transition method.

#### ***Year Ended December 31, 2005 Compared To The Year Ended December 31, 2004***

##### *Overview*

Net loss in 2005 was \$510,000 compared to net income in 2004 of \$152,000, while operating income was \$277,000 in 2005 compared to an operating loss of \$314,000 in 2004. Revenue increased \$829,000 to a record level of \$19,762,000 in 2005, with a corresponding gross profit increase of \$460,000 to \$11,669,000 in 2005, primarily due to volume increases in domestic reagent revenue as well as an increase in international antigen sales. Additionally, income from operations significantly improved due to a \$860,000 reduction in general and administrative expenses, caused principally by the \$1,690,000 bad debt recovery recorded when we reduced our allowance for doubtful accounts to recognize the impact of the May 12, 2005 collection of previously outstanding Italian accounts receivable from hospitals located within a particular region in Italy. Partially offsetting this reduction in general and administrative expenses was a \$580,000 charge to general and administrative expenses for compensation expense and related payroll taxes recorded as a result of our cancellation of 499,398 options to purchase shares of our common stock, which were granted under our 1999 Stock Option Plan, in exchange for a payment to participating option holders pursuant to the previously disclosed July 2005 program that we had offered. The overall decrease in our general and administrative expense was partially offset by an increase of \$295,000 in selling expenses as well as an increase of \$433,000 in research and development expenses related to the PARSEC® System. Our tax provision in 2005 was \$1,077,000 compared to a tax benefit of \$19,000 in 2004, with the increase primarily due to the recognition of deferred taxes in 2005 related to the impact of the collection of previously outstanding Italian accounts receivable and the creation of a valuation allowance to fully reserve the remaining foreign net deferred tax assets. Additionally, in 2005, other income decreased \$158,000 from 2004.

### Net Revenues And Gross Profit

	2005	2004	Period over Period Increase
Net Revenues Excluding Intercompany Sales			
Domestic .....	\$12,897,000	\$12,112,000	\$785,000
Italian .....	6,865,000	6,821,000	44,000
Total .....	19,762,000	18,933,000	829,000
Cost of Sales .....	8,093,000	7,724,000	369,000
Gross Profit .....	<u>\$11,669,000</u>	<u>\$11,209,000</u>	<u>\$460,000</u>
% of Total Net Revenues .....	59.0%	59.2%	

Net revenues in 2005 increased \$829,000, or 4.4%, from 2004. This increase was comprised of increases in external net revenues of \$785,000 from domestic operations and \$44,000 from Italian operations. Domestic external net revenues in 2005 increased by 6.5% from 2004. This increase was primarily due to greater revenue derived from volume increases in domestic reagent and international antigen revenue, partially offset by reductions caused by year-end backorders of certain diagnostic test kits and decreased revenue from a lower volume of instrument sales. The slight increase in external net revenues from Italian operations was primarily attributable to volume increases in reagent sales that were substantially offset by price reductions. Revenue fluctuations of the United States dollar relative to the Euro, as further discussed in "Currency Fluctuations" below, were insignificant. Gross profit in 2005 increased \$460,000, or 4.1%, from the prior year and was primarily attributable to the increase in net revenues. Gross profit as a percentage of net revenues was relatively unchanged in 2005 compared to 2004. The positive trends of an increase in manufacturing efficiencies gained from an increase in domestic reagent and international antigen revenue, as well as a decrease in expenses related to the amortization of equipment on lease, were offset by increased labor and regulatory consulting costs incurred in 2005 in an effort to improve our domestic production and quality operations.

### Operating Expenses

	2005	% of Revenue	2004	% of Revenue	Period over Period Increase (Decrease)
Selling Expenses					
Domestic .....	\$ 3,621,000	18.3%	\$ 3,529,000	18.6%	\$ 92,000
Italian .....	2,486,000	12.5%	2,283,000	12.1%	203,000
Total .....	6,107,000	30.9%	5,812,000	30.7%	295,000
General and Administrative .....	3,519,000	17.8%	4,379,000	23.1%	(860,000)
Research and Development .....	1,766,000	8.9%	1,333,000	7.0%	433,000
Total Operating Expenses .....	<u>\$11,392,000</u>	57.6%	<u>\$11,524,000</u>	60.9%	<u>\$(132,000)</u>

The most significant variation in operating expenses occurred as general and administrative expenses decreased by \$860,000 principally as a result of a bad debt recovery of Italian accounts receivable resulting from the impact of a May 12, 2005 payment of previously outstanding accounts receivable balances from hospitals located within a particular region in Italy. A significant portion of this approximately 2,000,000 Euro payment related to accounts receivable against which we had previously established allowances. As a result, we recognized a \$1,690,000 bad debt recovery, which is included in general and administrative expenses, as we reduced our allowance for doubtful accounts to recognize the impact of this collection of these receivables. Partially offsetting this reduction in general and administrative expenses was approximately \$580,000 in domestic compensation expense and related payroll taxes recorded as a result of our cancellation of 499,398 options to purchase shares of our common stock, which were granted under our 1999 Stock Option Plan, in exchange for a payment to participating option holders pursuant to a July 2005 program that we had offered, as further described in "Liquidity and Capital Resources" below. Partially offsetting the decrease in general and

administrative expenses was an increase of \$295,000 in selling expenses in 2005 compared to 2004. The increase of \$203,000 in the Italian portion of selling expenses was primarily due to the effect of increased payroll and consulting costs principally due to the marketing and promotion of the PARSEC® System. Domestic selling expenses increased \$92,000, primarily as a result of increased instrumentation and technical service costs, partially offset by lower sales force payroll costs. Research and development expenses increased \$433,000 due to an increase in Italian research and development expenses to \$888,000 in 2005 from \$539,000 in 2004, along with an increase in domestic research and development expenses to \$878,000 in 2005 from \$794,000 in 2004. The increase in research and development expenses was primarily the result of increased Italian research and development expenses related to the PARSEC® System, principally due to increased consulting and payroll costs. The future level of research and development expenditures 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.

#### *Income (Loss) From Operations*

Income from operations was \$277,000 in 2005 compared to a net loss from operations of \$314,000 in 2004. Excluding intersegment elimination adjustments, which decreased consolidated income from operations by \$8,000, income from operations in 2005 was composed of income from Italian operations of \$971,000, which includes the effect of the bad debt recovery of Italian accounts receivable in May 2005, offset by a loss from domestic operations of \$686,000, which includes the effect of the compensation expense relating to our cancellation of stock options pursuant to our July 2005 program. Excluding intersegment elimination adjustments, which decreased consolidated loss from operations by \$137,000, the loss from operations in 2004 was composed of a loss from domestic operations of \$224,000 and a loss from Italian operations of \$227,000.

#### *Other Income, Net*

Interest income increased to \$352,000 in 2005 from \$223,000 in 2004 primarily due to higher interest rates. Other expense, net totaled \$62,000 during 2005, compared to other income, net of \$225,000 in 2004. Amounts included in other income, net in 2005 and 2004 were primarily net foreign currency gains and losses on transactions, particularly by our Italian subsidiary, which were denominated in currencies other than a subsidiary's functional currency.

#### *Income Tax Provision (Benefit)*

During 2005 we recorded an income tax provision of \$1,077,000 compared to an income tax benefit of \$19,000 in 2004. The tax provision in 2005 was recognized by our Italian operation and is composed primarily of deferred taxes related to the allowance for doubtful accounts that was reduced during the first quarter of 2005 as a result of the May 12, 2005 collection of certain previously reserved Italian accounts receivable and the creation of a valuation allowance to fully reserve the remaining foreign net deferred tax assets. The tax benefit in 2004 was realized by our Italian operation as a result of before tax losses in Italy. No domestic tax provision was recorded in 2005 due to the establishment of a full valuation allowance against the benefit of domestic losses or in 2004 due to the expected utilization of prior period net operating losses to offset domestic taxable income in those periods.

#### *Net Income (Loss)*

We generated a net loss of \$510,000 in 2005 compared to a net income of \$152,000 in 2004. Our net loss per basic and diluted common share was \$0.02 in 2005 compared to net income per basic and diluted common share of \$0.01 in 2004. The net loss in 2005 and the net income in 2004 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 the calculation of earnings (loss) per share.

## Liquidity and Capital Resources

At December 31, 2006, our working capital was \$18,365,000 compared to \$20,036,000 at December 31, 2005 and \$22,993,000 at December 31, 2004. Cash and cash equivalents totaled \$1,996,000 at December 31, 2006, \$11,480,000 at December 31, 2005 and \$7,493,000 at December 31, 2004. Short-term marketable securities were \$6,650,000 at December 31, 2006, \$122,000 at December 31, 2005 and \$4,650,000 at December 31, 2004. Our short-term marketable securities are primarily investments in auction rate debt securities with final maturities longer than one year, but with interest rates typically resetting every 28 or 35 days through an auction mechanism. These short-term marketable securities consist primarily of taxable municipal bonds and government agency securities and were deemed short-term, classified as available for sale securities and recorded at cost, which approximated market value based on quoted market prices. Substantially all cash and cash equivalents and short-term marketable securities are presently held at one national securities brokerage firm. 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 only invest in select money market instruments, municipal securities and corporate issuers.

Net cash flows of \$1,364,000 were used by operating activities during 2006, compared to \$1,523,000 that was provided by operating activities in 2005 and \$22,000 that was provided by operating activities in 2004. 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. Cash provided by operating activities during 2005 was primarily attributable to \$15,000 from the combination of net loss and the non-cash items of depreciation and amortization, the deferred income tax provision, the provision for losses on accounts receivable, and compensation expense relating to our cancellation of stock options pursuant to our July 2005 program, as well as to \$1,327,000 from cash provided from a net working capital decrease, excluding the change in cash balance. This decrease in net working capital was principally due to the 2005 collection of Italian accounts receivable, partially offset by the resulting required value-added tax payment and increases in inventories, primarily for components necessary for the future production of the PARSEC® System. Cash provided by operating activities during 2004 was primarily the result of \$1,256,000 from the combination of net income and the non-cash items of depreciation and amortization, provision for losses on accounts receivable, and income tax benefit, offset by \$1,355,000 from cash used to increase net working capital, excluding the change in cash balance. This increase in net working capital was principally due to increases in accounts receivable and inventories, particularly components necessary for the future production of the PARSEC® System, as well as an increase in other current assets.

Net cash of \$8,070,000 was used by investing activities during 2006, compared to net cash of \$3,467,000 that was provided by investing activities during 2005 and \$7,218,000 that was provided during 2004. The decrease in cash provided by investing activities in 2006 compared to 2005 and 2004 was primarily the result of our net investments in marketable securities. Additionally, we paid approximately \$524,000 in 2006 and \$278,000 during 2005 as the result of a license agreement we entered into in September 2004 with an Italian diagnostics company to obtain a perpetual, worldwide, royalty-free license of product technology presently used by the Italian diagnostics company to manufacture hepatitis products currently sold by them. Under this license agreement, we agreed to pay four milestone payments totaling 1,000,000 Euro upon the Italian diagnostics company's achievement of certain enumerated performance objectives. In March 2005, we paid the first of these milestone payments, in the amount of \$277,717. As a result of the satisfaction of the first milestone, 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. The outstanding balance of this accrued license payable was \$947,920 in the accompanying consolidated balance sheet as of

December 31, 2005. In September 2006, these 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 milestone, a 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. The Italian diagnostics company is now working to achieve the two remaining performance objectives on or prior to May 2007 and October 2007, respectively. Among other events and actions included in these future milestones are 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 two remaining milestone payments 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 be able to manufacture our own hepatitis products. Additionally, the increase in cash used for investing activities in 2006 was also the result of an increase in capital expenditures that occurred in Italy as a result of moving our Italian operations to a new facility and purchasing equipment which we expect to be necessary for our anticipated production of the previously mentioned hepatitis products.

Net cash of \$34,000 was provided by financing activities during 2006, compared to the \$992,000 that was used by financing activities during 2005 and \$2,579,000 that was used by financing activities during 2004. In 2006, cash was provided from the exercise of 26,333 options granted under our stock option plans. In 2005, cash of \$789,000 was provided from the exercise of 683,397 options granted under our stock option plans, including the effect of our July 2005 program, described in Note 10, *Shareholders' Equity*, in the Notes to Consolidated Financial Statements, which we offered to each remaining holder of options granted under our 1999 Stock Option Plan. As a result of this program we received \$365,000 from the exercise of 499,397 options and used \$1,608,000 for the cancellation of options to purchase shares of our common stock. The remaining \$424,000 of the total of \$789,000 that was received from the exercise of stock options during 2005 was provided as a result of the exercise of 184,000 options granted under our other stock option plan, while \$50,000 was received in 2004 from the exercise of 17,625 options. Other financing activities during 2005 and 2004 included the repurchase of our common stock. In June 2005 we used \$173,000 to purchase and redeem from an unaffiliated stockholder 50,000 shares of our common stock as part of the common stock repurchase program approved by our Board of Directors in May 2002. These shares were retired and resumed the status of authorized and unissued shares. In 2004, we used \$2,629,000 to purchase and redeem 657,125 shares of our common stock from a group of three unaffiliated stockholders at an exercise price of \$4.00 per share in accordance with the terms of a previously announced redemption agreement. These shares were retired and also resumed the status of authorized and unissued shares.

Our product research and development expenditures are expected to be approximately \$2,400,000 during 2007. 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 \$400,000 will be required in 2007 to improve and expand our facilities, equipment and information systems. Included in these improvements are anticipated purchases of equipment that will be necessary to integrate the acquisition of technology expected to be received by us under our license agreement with an Italian diagnostics company for the license to us of product technology useful for our own manufacture of hepatitis products. 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 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 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 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. On May 12, 2005, we received a payment of approximately 2,000,000 Euro from a governmental region in Italy in satisfaction of previously outstanding accounts receivable balances from hospitals located in the region. A significant portion of this payment related to accounts receivable against which we had previously established allowances. In order to recognize the impact of this collection of receivables, we reduced our allowance for doubtful accounts. In August 2006, we received approximately 565,000 Euro in a similar transaction from a governmental region in Italy in satisfaction of previously outstanding accounts receivable balances from hospitals located in the region. We had anticipated collection of these amounts through a payment as described above and had therefore not provided 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, or if we require additional allowances, 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.

*Contractual Obligations.* The following table summarizes our significant contractual obligations as of December 31, 2006, and the effect such obligations are expected to have on our liquidity and cash flows in future periods.

	Total	Payments due by period			
		Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
Operating lease obligations . . . . .	\$2,226,000	\$529,000	\$867,000	\$830,000	\$ —
Other long-term obligations . . . . .	1,458,000	—	109,000	86,000	1,263,000
Total contractual cash obligations . . . . .	<u>\$3,684,000</u>	<u>\$529,000</u>	<u>\$976,000</u>	<u>\$916,000</u>	<u>\$1,263,000</u>

The expected timing of payment of the obligations described in the table above is estimated based on current information. Timing of payments and actual amounts paid may be different depending on a number of factors.

*Off-Balance Sheet Arrangements.* As of December 31, 2006, we had no off-balance sheet arrangements that are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material.

**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 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, the receipt of payments similar to those we received in May 2005 (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) and August 2006 (See *Liquidity and Capital Resources*) from governmental regions in Italy are possible. 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 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 \$1,093,000 and \$974,000 at December 31, 2006 and 2005, respectively. A provision for losses on accounts receivable of \$223,000 was recorded in 2006 and a provision for losses on accounts receivable of \$20,000 was recorded in 2004. A recovery of doubtful accounts receivable of \$1,833,000, primarily due to the recovery of \$1,690,000 discussed in Note 2, Summary of Significant Accounting Policies in the accompanying Notes to the Consolidated Financial Statements, was recorded in 2005.

#### *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. These estimates of future instrumentation and diagnostic kit product demand may prove to be inaccurate, in which case any resulting adjustments to the value of inventory would be recognized in our cost of goods sold at the time of such determination and could adversely affect our operating results. Inventory reserves were \$421,000 and \$332,000 as of December 31, 2006 and 2005, respectively. During 2006, \$371,000 was charged to cost and expenses while \$301,000 was charged in 2005 and \$143,000 was charged in 2004. Included within our inventory balance at December 31, 2006 was approximately \$1,264,000 in PARSEC® instrumentation and instrument components in anticipation of our pending full commercial product launch. A portion or all of this PARSEC® related inventory may become obsolete in the event future design changes are made to the PARSEC® System, improved instrument versions of the PARSEC® System are developed, or our estimates of future demand prove to be inaccurate. The impact of any such obsolescence could adversely affect our operating results.

#### *Goodwill And Other Intangibles*

Pursuant to SFAS No. 142, *Goodwill and Other Intangible Assets*, 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, 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.

### *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 123(R), we accounted for stock-based compensation in accordance with 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 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 domestic deferred tax assets as of December 31, 2006. Additionally, we have no net foreign deferred tax asset, as a full valuation allowance was established in March 2005 as a result of recent 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 July 2006, the Financial Accounting Standards Board, or FASB, issued FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an interpretation of FASB Statement No. 109*, or 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. This Interpretation is effective for fiscal years beginning after December 15, 2006. We are currently evaluating the effect this Interpretation will have on our financial position, liquidity and statement of operations, but do not expect the effect to be significant.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, or 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. 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.

On September 29, 2006, the FASB issued FASB Statement No. 158, *Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans, and amendment of FASB Statements Nos. 87, 88, 106 and 132(R)*, or FAS 158. FAS 158 requires companies to recognize a net liability or asset to report the funded status of their defined benefit pension and post retirement benefit plans. We do not have any defined benefit plans and therefore the effect of adoption at December 31, 2006 has not had an impact on our financial condition, results of operations or cash flows.

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*," or 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:

	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

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*, 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. 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, 2006, 2005 and 2004, approximately 33.1%, 34.7% and 36.0%, 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 \$68,000 in net revenues in 2006 compared to 2005 and \$4,000 in net revenues in 2005 compared to 2004. During the three years ended December 31, 2006, no subsidiary was domiciled in a highly inflationary environment and the impact of inflation and changing prices on our net sales and revenues and on loss from continuing operations was not material.

During 2006, our subsidiary in Italy generated 33.1% 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.

### **Income Taxes**

We recognized an income tax provision (benefit) of \$153,000, \$1,077,000 and \$(19,000) for the years ended December 31, 2006, 2005 and 2004, respectively, which related to foreign operations. Through March 14, 2001, we reported our 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 Diagnostics, we were no longer included in the consolidated income tax returns of IVAX.

For financial statement purposes, we accounted for income taxes on a stand-alone basis as though we had filed our own income tax returns. 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. Our income tax provision for the year ended December 31, 2005 was different from the amount computed on the income before income taxes at the statutory rate of 35% primarily due to an increase in the valuation allowance, including the creation of a foreign valuation allowance in the year ended December 31, 2005 to fully reserve the remaining foreign deferred tax asset due to the recent losses by our Italian operation. The 2005 current income tax was the result of Italian local income taxes based upon applicable statutory rates effective in Italy.

As of December 31, 2006, we had no net domestic deferred tax asset, as domestic net operating losses generated prior to the merger 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, 2006, we had net deferred tax liabilities relating to tax deductible goodwill of \$572,000, \$509,000 of which was recorded at January 1, 2006 as a result of applying SAB 108 using the cumulative effect transition method. At December 31, 2006, we also had no net foreign deferred tax asset due to the creation of a foreign valuation allowance in the first quarter of 2005 to fully reserve the remaining foreign deferred tax asset due to recent 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**

Market risk represents the risk of loss that may impact our consolidated financial position, results of operations or cash flows. In the normal course of doing business, we are exposed to the risks associated with foreign currency exchange rates and changes in interest rates.

*Foreign Currency Exchange Rate Risk.* We are exposed to exchange rate risk when our Italian subsidiary enters into transactions denominated in currencies other than its functional currency. For additional information about foreign currency exchange rate risk, see "Currency Fluctuations" in our Management's Discussion and Analysis of Financial Condition and Results of Operation.

*Interest Rate Risk.* We do not have debt obligations and we do not believe the interest rate exposure related to our investments to be material.

*Commodity Price Risk.* We do not believe we are subject to any material risk associated with commodity prices.

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

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES  
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

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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 accompanying consolidated balance sheet and the related consolidated statements of operations, shareholders' equity and cash flows present fairly, in all material respects, the financial position of IVAX Diagnostics, Inc. (the "Company") and its subsidiaries at December 31, 2006, and the results of their operations and their cash flows for the year ended December 31, 2006 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule for the year ended December 31, 2006 listed in the index appearing under Item 15(a)(2), presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. 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 audit. We conducted our audit 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 audit provides 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 30, 2007

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders  
of IVAX Diagnostics, Inc.

We have audited the accompanying consolidated balance sheet of IVAX Diagnostics, Inc. (a Delaware corporation and 72%-owned subsidiary of IVAX Corporation, which is wholly-owned by Teva Pharmaceutical Industries Limited) and subsidiaries as of December 31, 2005, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the two years in the period ended December 31, 2005. Our audits also included the financial statement schedule for each of the two years in the period ended December 31, 2005 listed in the Index at Item 15(a). These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also 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.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of IVAX Diagnostics, Inc. and subsidiaries at December 31, 2005, and the consolidated results of their operations and their cash flows for each of the two years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule for each of the two years in the period ended December 31, 2005, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ Ernst & Young LLP  
Certified Public Accountants

Miami, Florida  
March 13, 2006

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**CONSOLIDATED BALANCE SHEETS**  
**DECEMBER 31, 2006 AND 2005**

	<b>2006</b>	<b>2005</b>
<b><u>ASSETS</u></b>		
<b>CURRENT ASSETS:</b>		
Cash and cash equivalents .....	\$ 1,995,730	\$11,479,568
Marketable securities .....	6,650,000	122,045
Accounts receivable, net of allowances for doubtful accounts of \$1,093,070 and \$973,855, respectively .....	7,489,272	6,695,353
Inventories, net .....	5,557,528	5,608,584
Other current assets .....	1,183,571	1,164,890
Total current assets .....	22,876,101	25,070,440
<b>PROPERTY, PLANT AND EQUIPMENT:</b>		
Land .....	352,957	352,957
Buildings and improvements .....	2,985,081	2,711,785
Machinery and equipment .....	2,825,404	2,968,885
Furniture and fixtures .....	1,788,170	1,397,936
	7,951,612	7,431,563
Less—Accumulated depreciation .....	(5,650,032)	(5,217,982)
	2,301,580	2,213,581
<b>OTHER ASSETS:</b>		
Goodwill .....	6,722,725	6,722,725
Equipment on lease, net .....	386,762	585,295
Product license .....	1,255,936	1,255,936
Other .....	163,998	55,553
	8,529,421	8,619,509
Total assets .....	\$ 33,707,102	\$35,903,530
<b><u>LIABILITIES AND SHAREHOLDERS' EQUITY</u></b>		
<b>CURRENT LIABILITIES:</b>		
Accounts payable .....	\$ 935,896	\$ 1,190,204
Accrued license payable .....	526,800	947,920
Accrued expenses .....	3,048,285	2,895,836
Total current liabilities .....	4,510,981	5,033,960
<b>OTHER LONG-TERM LIABILITIES:</b>		
Deferred tax liabilities .....	572,089	—
Other long-term liabilities .....	885,890	680,006
Total other long-term liabilities .....	1,457,979	680,006
<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 2006 and 27,623,554 in 2005 .....	276,498	276,235
Additional paid-in capital .....	40,781,825	40,548,950
Accumulated deficit .....	(12,776,202)	(9,458,371)
Accumulated other comprehensive loss .....	(543,979)	(1,177,250)
Total shareholders' equity .....	27,738,142	30,189,564
Total liabilities and shareholders' equity .....	\$ 33,707,102	\$35,903,530

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, 2006, 2005 AND 2004**

	<u>2006</u>	<u>2005</u>	<u>2004</u>
NET REVENUE .....	\$19,523,471	\$19,761,807	\$18,933,468
COST OF SALES .....	8,457,855	8,092,617	7,724,076
Gross profit .....	<u>11,065,616</u>	<u>11,669,190</u>	<u>11,209,392</u>
OPERATING EXPENSES:			
Selling .....	5,883,610	6,107,462	5,811,803
General and administrative .....	5,652,392	3,518,926	4,378,915
Research and development .....	2,403,971	1,765,998	1,333,079
Total operating expenses .....	<u>13,939,973</u>	<u>11,392,386</u>	<u>11,523,797</u>
Income (loss) from operations .....	<u>(2,874,357)</u>	<u>276,804</u>	<u>(314,405)</u>
OTHER INCOME, NET:			
Interest income .....	463,882	352,304	223,230
Other income (expense), net .....	(44,380)	(62,048)	224,775
Total other income, net .....	<u>419,502</u>	<u>290,256</u>	<u>448,005</u>
Income (loss) before income taxes .....	(2,454,855)	567,060	133,600
INCOME TAX PROVISION (BENEFIT) .....	<u>153,379</u>	<u>1,076,587</u>	<u>(18,660)</u>
INCOME (LOSS) BEFORE CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE .....	(2,608,234)	(509,527)	152,260
CUMULATIVE EFFECT OF CHANGE IN ACCOUNTING PRINCIPLE .....	<u>(201,000)</u>	<u>—</u>	<u>—</u>
Net income (loss) .....	<u><u>\$ (2,809,234)</u></u>	<u><u>\$ (509,527)</u></u>	<u><u>\$ 152,260</u></u>
Earnings (loss) per share, before cumulative effect of change in accounting principle			
Basic and diluted .....	<u>\$ (0.09)</u>	<u>\$ (0.02)</u>	<u>\$ 0.01</u>
Cumulative effect of change in accounting principle, per share			
Basic and diluted .....	<u>\$ (0.01)</u>	<u>\$ —</u>	<u>\$ —</u>
Net income (loss) per share			
Basic and diluted .....	<u>\$ (0.10)</u>	<u>\$ (0.02)</u>	<u>\$ 0.01</u>
WEIGHTED AVERAGE SHARES OUTSTANDING:			
Basic .....	<u>27,639,221</u>	<u>27,295,176</u>	<u>27,341,043</u>
Diluted .....	<u>27,639,221</u>	<u>27,295,176</u>	<u>28,542,970</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, 2006, 2005 AND 2004**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
	Shares	Amount				
BALANCE, December 31, 2003	27,659,329	\$276,593	\$43,582,346	\$ (9,101,104)	\$ (794,553)	\$33,963,282
Comprehensive income:						
Net income	—	—	—	152,260	—	152,260
Translation adjustment	—	—	—	—	509,130	509,130
Comprehensive income						661,390
Repurchase of common stock	(657,125)	(6,571)	(2,621,929)	—	—	(2,628,500)
Exercise of stock options	17,625	176	49,624	—	—	49,800
BALANCE, December 31, 2004	27,019,829	270,198	41,010,041	(8,948,844)	(285,423)	32,045,972
Comprehensive loss:						
Net loss	—	—	—	(509,527)	—	(509,527)
Translation adjustment	—	—	—	—	(891,827)	(891,827)
Comprehensive loss						(1,401,354)
Repurchase of common stock	(50,000)	(500)	(172,000)	—	—	(172,500)
Exercise of stock options	653,725	6,537	782,118	—	—	788,654
Cancellation of stock options	—	—	(1,071,209)	—	—	(1,071,208)
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	<u>27,649,887</u>	<u>\$276,498</u>	<u>\$40,781,825</u>	<u>\$(12,776,202)</u>	<u>\$ (543,979)</u>	<u>\$27,738,142</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, 2006, 2005 AND 2004**

	<u>2006</u>	<u>2005</u>	<u>2004</u>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Net income (loss) .....	\$ (2,809,234)	\$ (509,527)	\$ 152,260
Adjustments to reconcile net income (loss) to net cash provided by operating activities-			
Depreciation and amortization .....	799,040	828,455	1,183,028
Provision for (recovery of) doubtful accounts receivable .....	222,652	(1,832,911)	20,063
Compensation expense relating to stock option cancellation .....	—	536,672	—
Non-cash compensation .....	20,664	—	—
Deferred income tax provision (benefit) .....	63,492	992,564	(99,521)
Cumulative effect of a change in accounting principle .....	201,000	—	—
Write-off of certain PARSEC instrumentation assets, including prior period depreciation .....	509,000	—	—
Disposal of assets .....	35,402	—	—
Changes in operating assets and liabilities:			
Accounts receivable .....	(485,361)	2,166,743	(661,257)
Inventories .....	238,192	(776,745)	(509,665)
Other current assets .....	86,587	(161,353)	(307,431)
Other assets .....	(97,665)	46,961	6,816
Accounts payable and accrued expenses .....	(249,998)	98,566	123,213
Other long-term liabilities .....	102,356	133,207	114,967
Net cash provided by operating activities .....	<u>(1,363,873)</u>	<u>1,522,632</u>	<u>22,473</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Capital expenditures .....	(881,828)	(350,597)	(406,787)
Acquisition of equipment on lease .....	(145,244)	(432,462)	(325,448)
Acquisition of product license .....	(523,840)	(277,717)	—
Purchases of marketable securities .....	(8,750,000)	(14,603,587)	(1,750,000)
Proceeds from sales of marketable securities .....	2,230,918	19,131,543	9,700,000
Net cash provided by (used in) investing activities .....	<u>(8,069,994)</u>	<u>3,467,180</u>	<u>7,217,765</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from stock option exercises .....	34,473	788,654	49,800
Cancellation of stock options .....	—	(1,607,880)	—
Repurchase of common stock .....	—	(172,500)	(2,628,500)
Net cash (used in) provided by financing activities .....	<u>34,473</u>	<u>(991,726)</u>	<u>(2,578,700)</u>
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS .....	<u>(84,444)</u>	<u>(11,403)</u>	<u>(33,492)</u>
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS .....	(9,483,838)	3,986,683	4,628,046
CASH AND CASH EQUIVALENTS, beginning of year .....	<u>11,479,568</u>	<u>7,492,885</u>	<u>2,864,839</u>
CASH AND CASH EQUIVALENTS, end of year .....	<u>\$ 1,995,730</u>	<u>\$ 11,479,568</u>	<u>\$ 7,492,885</u>
<b>SUPPLEMENTAL DISCLOSURES:</b>			
Interest paid .....	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>
Income taxes paid .....	<u>\$ 90,357</u>	<u>\$ —</u>	<u>\$ 318,686</u>
<b>NONCASH INVESTING ACTIVITY:</b>			
Acquisition of product license .....	<u>\$ —</u>	<u>\$ 1,030,000</u>	<u>\$ —</u>

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"), the Company's approximately 72.3% stockholder, 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, warranty obligations, stock based compensation, the realization of long-lived assets and contingencies and litigation.

*Recently Issued Accounting Standards*

In July 2006, the Financial Accounting Standards Board ("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. This Interpretation is effective for fiscal years beginning after December 15, 2006. The Company is currently evaluating the effect this Interpretation will have on the Company's financial position, liquidity and statement of operations, but does not expect the effect to be significant.

In September 2006, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 157, *Fair Value Measurements* ("SFAS No. 157"). SFAS No. 157 establishes a framework for measuring fair value and

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES**

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

expands the disclosures on fair value measurements. SFAS No. 157 is effective for fiscal years beginning after November 15, 2007. The Company is currently evaluating the impact of the adoption of SFAS No. 157 on its consolidated financial statements. However, it does not expect the effect to be significant.

On September 29, 2006, the FASB issued FASB Statement No. 158, *Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans, and amendment of FASB Statements Nos. 87, 88, 106 and 132(R)* ("FAS 158"). FAS 158 requires companies to recognize a net liability or asset to report the funded status of their defined benefit pension and post retirement benefit plans. The Company does not have any funded defined benefit plans and therefore the effect of adoption at December 31, 2006 has not had an impact on its financial condition, results of operations or cash flows.

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 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:

	<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

## IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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. It is effective as of the first interim or annual reporting period that begins after June 15, 2005 and requires companies to expense the fair value of all awards that have future vesting provisions, are modified, or are newly granted beginning on the grant date of such options. The cumulative effect of the initial application of this statement, if any, is to be recognized as of the effective date. SFAS 123(R) can be adopted under two methods, the modified prospective or the modified retrospective applications. Under the modified prospective application, compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding as of the effective date should be recognized as the requisite service is rendered on or after the effective date. The compensation cost for that portion of awards should be based on the grant-date fair value of those awards as calculated for either recognition or pro forma disclosure under SFAS No. 123. Changes to the grant-date fair value of awards granted before the effective date of this Statement are precluded. The compensation cost for those earlier awards should be attributed to periods beginning on or after the effective date of this Statement using the attribution method that was used under SFAS No. 123, except that the method of recognizing forfeitures only as they occur should be discontinued. Any unearned or deferred compensation related to those earlier awards should be eliminated against the appropriate equity accounts. The modified retrospective application may be applied to all prior years that SFAS No. 123 was effective or only to prior interim periods in the year of initial adoption if the effective date of SFAS 123(R) does not coincide with the beginning of the fiscal year. Effective April 21, 2005, the Securities and Exchange Commission issued an Amendment to Rule 4-01(a) of Regulation S-X regarding the compliance date for SFAS 123(R). Under the amendment, registrants are required to file financial statements that comply with SFAS 123(R) the first quarter of the first fiscal year beginning after June 15, 2005. 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 Securities*

The Company only invests in select money market instruments, municipal securities and corporate issuers. It is the Company's intent to maintain a liquid portfolio to take advantage of investment opportunities. In the years ended December 31, 2006 and 2005, available cash was typically invested in auction rate securities with final maturities longer than one year, but with interest rates resetting every 28 or 35 days through an auction mechanism. These short-term marketable securities consist primarily of taxable municipal bonds and government

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

agency securities and were deemed short-term, classified as available for sale securities and recorded at cost which approximated market value based on quoted market prices. Realized gains and losses from sales of marketable securities are based on the specific identification method. For the years ended December 31, 2006, 2005 and 2004, realized gains and losses were not material, as recorded book value approximated fair value. The Company received proceeds of \$2,230,918, \$19,131,543 and \$9,700,000 for the sale of marketable securities, and used \$8,750,000, \$14,603,587 and \$1,750,000 for the purchase of marketable securities in 2006, 2005 and 2004, respectively. Included in marketable securities at December 31, 2005 were \$122,045 in Italian bank bonds held by the Company's Italian subsidiary that were used to support guarantees provided by the Company.

The contractual maturity dates of the Company's investments in marketable securities invested in auction rate securities at December 31, 2006 range from 2027 to 2045. The expected maturities may differ from contractual maturities because certain borrowers have the right to call or prepay obligations with and without prepayment penalties.

*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 uncollectible accounts, while subsequent recoveries are netted against provision for doubtful accounts expense. The Company does not charge interest on accounts receivable.

On May 12, 2005, the Company received a payment of approximately 2,000,000 Euro from a governmental region in Italy in satisfaction of previously outstanding accounts receivable balances from hospitals located in the region. A significant portion of this payment related to accounts receivable against which the Company had previously established allowances. In order to recognize the impact of the collection of these receivables, the Company reduced its allowance for doubtful accounts and recognized a corresponding bad debt recovery of \$1,690,000 that is included as a reduction of general and administrative expenses in the accompanying consolidated statement of operations for the year ended December 31, 2005. In August 2006, the Company received approximately 565,000 Euro in a similar transaction from a governmental region in Italy in satisfaction of previously outstanding accounts receivable balances from hospitals located in the region. The Company had anticipated collection of these amounts through a payment as described above and had therefore not provided an allowance for doubtful accounts for these amounts. Additional payments by governmental regions in Italy are possible, and, as a result, the Company may consider the potential receipt of those payments in determining our allowance for doubtful accounts.

The allowance for doubtful accounts was \$1,093,070, \$973,855 and \$3,080,952 at December 31, 2006, 2005 and 2004, respectively, and activity for the years then ended was as follows:

	<u>2006</u>	<u>2005</u>	<u>2004</u>
January 1 balance . . . . .	\$ 973,855	\$ 3,080,952	\$2,897,833
Provision (recovery) . . . . .	222,652	(1,832,911)	20,063
Write-offs . . . . .	(184,005)	(17,577)	(30,104)
Effects of changes in foreign exchange rates . . . . .	80,568	(256,609)	193,160
Balance at December 31 . . . . .	<u>\$1,093,070</u>	<u>\$ 973,855</u>	<u>\$3,080,952</u>

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES**

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

*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. 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>2006</u>	<u>2005</u>
Raw materials .....	\$1,190,933	\$1,472,994
Work-in-process .....	1,570,680	1,223,572
Finished goods .....	<u>2,795,915</u>	<u>2,912,018</u>
Total .....	<u>\$5,557,528</u>	<u>\$5,608,584</u>

Total inventories include components for current or future versions of products and instrumentation, including approximately \$1,264,000 and \$1,013,000 in PARSEC® System instrumentation and instrument components at December 31, 2006 and December 31, 2005, respectively, in anticipation of our pending full commercial product launch.

*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 \$447,813, \$306,011 and \$326,270 for the years ended December 31, 2006, 2005 and 2004, 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>2006</u>	<u>2005</u>
Equipment on lease, at cost .....	\$6,044,746	\$5,556,232
Less—Accumulated amortization .....	<u>5,657,984</u>	<u>4,970,937</u>
	<u>\$ 386,762</u>	<u>\$ 585,295</u>

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

Equipment on lease is amortized over three years. Amortization expense related to equipment on lease was \$351,227, \$514,110 and \$848,427 for the years ended December 31, 2006, 2005 and 2004, respectively.

*Long Lived Assets Including Goodwill*

Goodwill consists of the following:

	December 31,	
	2006	2005
Goodwill .....	\$9,139,755	\$9,139,755
Less—Accumulated amortization .....	2,417,030	2,417,030
	\$6,722,725	\$6,722,725

In accordance with SFAS 142, *Goodwill and Other Intangible Assets*, the Company performed its annual test of goodwill using a measurement date of December 31, 2006 and no impairments were noted.

In accordance with SFAS 144, *Accounting for the Impairment or Disposal of Long Lived Assets*, the Company continually evaluates whether events and circumstances have occurred that indicate that the remaining balance of long lived assets, excluding goodwill that is discussed above, may not be recoverable. When factors indicate that long lived assets excluding goodwill may be impaired, the Company uses various methods to estimate future cash flow, including current and projected levels of income, business trends, prospects and market conditions. If the sum of the expected future undiscounted net cash flows is less than the carrying amount of the asset, then an impairment loss is recognized based on the excess of the carrying amount over the estimated fair value of the asset. Any impairment amount is charged to operations.

*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.

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

*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, 2006, 2005 and 2004 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 and therefore has not restated prior periods' results. 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.

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

Additionally, 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. As of December 31, 2006, the resulting liability has been reduced to \$23,000, and the fair value adjustment of \$178,000 has been reported as a reduction of general and administrative expenses.

At December 31, 2006, 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 \$20,664 for the year ended December 31, 2006. As a result of adopting SFAS 123(R), the impact to the accompanying consolidated statement of operations for the year ended December 31, 2006 was \$20,664 lower for income before taxes and \$221,664 lower for net income, considering the cumulative effect adjustment disclosure above, than if the Company had continued to account for stock-based compensation under Accounting Principles Board ("APB") Opinion No. 25, Accounting for Stock Issued to Employees. The impact on both basic and diluted earnings per share for the year ended December 31, 2006 was \$(0.01). Prior to January 1, 2006 the Company accounted for these plans under the recognition and measurement of APB 25 and the Company provided pro-forma disclosure amounts in accordance with SFAS No. 148, Accounting for Stock-Based Compensation—Transition and Disclosure, as if the fair value method defined by the original provisions of SFAS 123 had been applied to its stock-based compensation.

The pro forma table below reflects net earnings and basic and diluted earnings per share for the years ended December 31, 2005 and 2004, had the Company applied the fair value recognition provisions of the original SFAS 123 as follows:

	<u>2005</u>	<u>2004</u>
Net income (loss) as reported .....	\$(509,527)	\$ 152,260
Add: Compensation expense from stock option cancellation .....	536,672	—
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards .....	(591,971)	(989,291)
Pro forma net loss .....	<u>\$(564,826)</u>	<u>\$(837,031)</u>
Pro forma basic and diluted loss per share .....	<u>\$ (0.02)</u>	<u>\$ (0.03)</u>
Reported basic and diluted income (loss) per share .....	<u>\$ (0.02)</u>	<u>\$ 0.01</u>
Pro forma weighted average fair value of options granted .....	<u>\$ 2.90</u>	<u>\$ 4.48</u>
Assumptions:		
Expected life (years) .....	2.8	3.0
Risk-free interest rate .....	3.8%	3.5%
Expected volatility .....	71%	74%
Dividend yield .....	—	—

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES**

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

*Comprehensive Income (Loss)*

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

	Year Ended December 31,		
	2006	2005	2004
Net income (loss) .....	\$ (2,809,234)	\$ (509,527)	\$ 152,260
Foreign currency translation adjustment .....	633,271	(891,827)	509,130
Comprehensive income (loss) .....	<u>\$ (2,175,963)</u>	<u>\$ (1,401,354)</u>	<u>\$ 661,390</u>

*Earnings (Loss) per Share*

Earnings (loss) per share is computed by dividing net income (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 earnings (loss) per share computation for the three years ended December 31, 2006 is as follows:

	December 31,		
	2006	2005	2004
Basic weighted average shares outstanding .....	27,639,221	27,295,176	27,341,043
Effect of diluted securities—			
Stock options and warrants .....	—	—	1,201,927
Diluted weighted average shares outstanding .....	<u>27,639,221</u>	<u>27,295,176</u>	<u>28,542,970</u>
Not included in the calculation of diluted earnings (loss) per share because their impact is antidilutive:			
Stock options and warrants outstanding .....	<u>819,549</u>	<u>922,532</u>	<u>793,815</u>

**3 WRITE-OFF OF CERTAIN PARSEC® ASSETS**

During the third quarter of 2006, the Company recorded a \$509,000 write-off of assets relating to the PARSEC® System, the Company's new proprietary instrument system which is currently pending full commercial release. 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, the Company recorded \$355,000 of this amount within research and development expenses, consisting of \$278,000 in assets associated with PARSEC® System development and \$77,000 in inventory. As part of this analysis the Company became aware of, and included in this adjustment in research and development expenses, errors in prior periods totaling \$134,000, 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, both income from operations and income before income taxes would have been lower by \$51,000, \$41,000 and \$42,000, respectively. The Company concluded that this adjustment did not have a material effect on the 2006 or previously filed financial statements.

**4 MERGER AND ACQUISITION**

On March 14, 2001, b2bstores.com Inc. ("b2bstores.com"), IVAX and the pre-merger IVAX Diagnostics, Inc., then a wholly-owned subsidiary of IVAX, consummated a merger (the "Merger") of the pre-merger

## IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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

As a result of the Merger, all non-qualified stock options previously granted to employees of the pre-merger Diagnostics under the IVAX Diagnostics, Inc. 1999 Stock Option Plan (see Note 10, *Shareholders' Equity*) were converted into non-qualified stock options to purchase 1,108,795 shares of the Company's common stock.

#### 5 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, 2006 and 2005, \$5,476,166 and \$4,633,747, respectively, of total net accounts receivable were due in Italy. At December 31, 2006 and 2005, 66.2% and 57.0%, respectively, of total net accounts receivable were due from hospitals and laboratories controlled by the Italian government.

Substantially all cash and cash equivalents and marketable securities are presently held at one national securities brokerage firm. 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.

#### 6 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 presently used by the Italian diagnostics company to manufacture hepatitis products currently sold by them. In exchange, the Company agreed to pay four milestone payments totaling 1,000,000 Euro upon the Italian diagnostics company's achievement of certain enumerated performance objectives. 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 milestone, 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. The outstanding balance of this accrued license payable was \$947,920 in the accompanying consolidated balance sheet as of December 31, 2005. In September 2006, these 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 milestone, a 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. The Italian diagnostics company is now working to achieve the two remaining performance objectives on or prior to May 2007 and October 2007, respectively. Among the other events and actions included in these future milestones are 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. Amortization of the product license will begin following the successful technology transfer and initial sale of hepatitis products manufactured by the Company.

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**7 INCOME TAXES**

The Company accounts for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes*. 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, 2006 and 2005, the Company had no net domestic deferred tax asset, as domestic net operating losses generated prior to the Merger 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, 2006, the Company had net deferred tax liabilities relating to tax deductible goodwill of \$572,089, \$508,597 of which was recorded at January 1, 2006 as a result of applying SAB 108 using the cumulative effect transition method. Additionally, as of December 31, 2006 and 2005, 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 recent losses by the Company's Italian operation, and additional allowances have been provided for losses occurring since that date through December 31, 2006. 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>2006</u>	<u>2005</u>	<u>2004</u>
Current:			
Domestic .....	\$ —	\$ —	\$ —
Foreign .....	89,887	84,023	80,861
Deferred:			
Domestic .....	63,492	—	—
Foreign .....	—	992,564	(99,521)
Total .....	<u>\$153,379</u>	<u>\$1,076,587</u>	<u>\$(18,660)</u>

The components of income (loss) before income taxes are as follows:

	<u>Year Ended December 31,</u>		
	<u>2006</u>	<u>2005</u>	<u>2004</u>
United States .....	\$ (226,634)	\$ (59,636)	\$ 297,352
Foreign .....	(2,228,221)	626,696	(163,752)
Total .....	<u>\$(2,454,855)</u>	<u>\$567,060</u>	<u>\$ 133,600</u>

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

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

	December 31,	
	2006	2005
Current:		
Accounts receivable allowances .....	\$ 334,874	\$ 332,561
Reserves and accruals .....	309,846	435,190
Capitalized inventory costs .....	137,245	142,444
Valuation allowance .....	(781,965)	(910,195)
Deferred income taxes .....	—	—
Long-Term:		
Depreciation and basis differences on fixed assets .....	(197,431)	(197,431)
Stock based compensation .....	85,341	—
Other .....	(40,061)	5,925
Foreign net operating losses .....	1,269,445	407,520
Domestic net operating losses .....	3,855,493	3,550,170
Valuation allowance .....	(4,972,787)	(3,766,184)
Net deferred tax asset .....	\$ —	\$ —

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

	December 31,	
	2006	2005
Long-Term:		
Tax deductible goodwill .....	572,089	—
Net deferred tax liability .....	\$572,089	\$ —

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,		
	2006	2005	2004
Provision (benefit) for income taxes at U.S. Federal statutory rate of 35% .....	\$(859,199)	\$ 198,471	\$ 46,760
Change in valuation allowance (excluding portion relating to stock options) .....	923,829	706,529	(104,073)
Foreign tax rate differential and global permanent differences .....	88,749	171,587	38,653
Provision (benefit) for income taxes .....	\$ 153,379	\$1,076,587	\$ (18,660)

The Company's income tax provision or benefit for the years ended December 31, 2006, 2005 and 2004 was different from the amount computed on the loss before provision (benefit) for income taxes at the statutory rate of 35% primarily due to the change in the valuation allowance, including the creation of a full foreign valuation allowance in the year ended December 31, 2005 and foreign tax rate differential and global permanent differences.

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES**

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

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, 2006, 2005 and 2004, the Company increased its valuation allowance by approximately \$1,078,000, \$1,530,000 and \$62,000, respectively. Net operating losses generated by the Company after March 14, 2001 total \$9,886,000, 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, \$2,438,000 and \$707,000 are available for use prior to their expirations in 2022, 2023, 2024, 2025 and 2026, respectively. Approximately \$3,710,000 of the domestic net operating loss at December 31, 2006, representing approximately \$1,300,000 (including approximately \$10,000, \$800,000 and \$100,000 for the three years ended December 31, 2006, 2005 and 2004, 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.

On October 22, 2004, the American Jobs Creation Act of 2004 was signed into law. Management has reviewed the provisions affecting us and has determined that it is not in our best interest to repatriate any foreign earnings at this time. Such earnings will continue to be reinvested into our foreign operations. The principal reason for deciding against repatriation at a low tax rate is the absence of excess cash in our foreign subsidiary.

**8 EMPLOYEE BENEFIT PLAN**

Beginning after the date of the Merger, 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 \$71,000, \$67,000 and \$68,000 were made into this plan during the years ended December 31, 2006, 2005 and 2004, respectively.

**9 ACCRUED EXPENSES**

Accrued expenses consist of the following:

	<u>December 31,</u>	
	<u>2006</u>	<u>2005</u>
Payroll costs .....	\$ 834,366	\$ 876,926
Taxes, other than income taxes .....	1,512,977	1,319,777
Professional fees .....	365,769	267,351
Royalties .....	81,995	76,264
Other .....	253,178	355,518
	<u>\$3,048,285</u>	<u>\$2,895,836</u>

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**10 SHAREHOLDERS' EQUITY**

*Common Stock*

Concurrent with the approval of the Merger, 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 2006, no shares of the Company's common stock were repurchased by the Company. During 2005, the Company purchased and redeemed a total of 50,000 shares of the Company's common stock at a price of \$3.45 per share in accordance with the terms of this repurchase program. These shares have been retired and have resumed the status of authorized and unissued shares. There were no share repurchases under this program during 2004. The total number of shares of common stock repurchased by the Company since the inception of its repurchase program is 1,184,573.

During 2004, the Company purchased and redeemed a total of 657,125 shares of the Company's common stock from a group of three unaffiliated stockholders at a price of \$4.00 per share under the terms of a previously announced Redemption Agreement. These shares have been retired and have resumed the status of authorized and unissued shares.

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

In connection with the initial public offering of b2bstores.com, the underwriters' representatives were issued warrants to purchase up to 400,000 shares of the Company's common stock at a price of \$13.20 per share. These warrants expired unexercised in February 2005.

Employees of the pre-merger Diagnostics were eligible to participate in the IVAX 1997 Employee Stock Option Plan, as amended (the "1997 Plan"), which permits the issuance of options to employees and consultants to purchase shares of IVAX common stock. The 1997 Plan provides that the exercise price of the issued options shall be no less than the fair market value of IVAX' common stock on the date of grant and that the option terms shall not exceed ten years. Since the approval of the Company's 1999 Stock Option Plan (discussed below), no option grants have been made to Company employees from the 1997 Plan. As of December 31, 2006, no options were outstanding to Company employees under the 1997 Plan.

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 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. During the year ended December 31, 2005, 181,500 options granted prior to the Merger under the Performance Plan were exercised and 118,500 options granted prior to the Merger under the Performance Plan were terminated. During the year ended December 31, 2004, there were no exercises or terminations of options granted under the Performance Plan prior to the Merger. Options granted prior to the Merger 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*

## IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

*Accounting Policies*, Note 10, *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, 2006.

#### *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 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, 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. As of December 31, 2004, 1,016,795 options to purchase shares of the Company's common stock were outstanding under the 1999 Plan. In July 2005, the Company offered each holder of these 1,016,795 options to purchase shares of the Company's common stock granted under the 1999 Plan, the opportunity to participate in a program whereby the Company would cancel 50% of such option holder's options in exchange for a cash payment to such holder of \$3.52 per share (except for the options of Giorgio D'Urso, the Company's Chief Executive Officer and President, for which he would receive a cash payment of \$3.02 per share), such option holder would then exercise all of his or her remaining options by paying to the Company the exercise price, and such option holder would agree to hold all of the shares of the Company's common stock received upon exercise for a period of at least one year. On July 22, 2005, pursuant to the Company's offer of this program, the Company entered into agreements with employees and a consultant of the Company and its subsidiaries, including, without limitation, the three executive officers of the Company. The participating option holders held a total of 998,795 options, all of which options were fully vested, had an exercise price of \$0.73 per share and had an expiration date in the second (and, in one case, the third) quarter of 2006. Pursuant to these agreements, during the third quarter of 2005, the Company cancelled 499,398 options in exchange for a payment to the participating option holders of \$1,607,880, the participating option holders exercised the remaining 499,397 options by paying to the Company the aggregate exercise price of approximately \$365,000, and each participating option holder agreed to hold all of the shares of the Company's common stock received upon exercise for a period of at least one year. The payment of \$1,607,880 to the participating option holders was recognized in the year ended December 31, 2005 as aggregate employment compensation expense of \$536,672 and as a reduction of capital in excess of par of \$1,071,208. 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 are outstanding under the 1999 Plan and 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, 2006, 819,549 options to purchase shares of the Company's common stock were outstanding under the Performance Plan. 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

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES**

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

exercisable over a ten year period were granted, and 1,650 options were terminated. During the year ended December 31, 2005, 165,000 options were granted under the Performance Plan, while, of the options granted after the consummation of the Merger, 2,500 options were exercised and 30,750 options were terminated. Additionally, during the year ended December 31, 2004, 205,349 options were granted under the Performance Plan, while, of the options granted after the consummation of the Merger, 17,625 options were exercised and 15,775 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 under the Performance Plan for options granted by the Company after the consummation of the Merger and transactions under the 1999 Plan:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>
Outstanding at December 31, 2003 .....	1,434,295	1.38
Granted .....	205,349	6.52
Terminated .....	(15,775)	2.90
Exercised .....	<u>(17,625)</u>	2.83
Outstanding at December 31, 2004 .....	1,606,244	2.01
Granted .....	165,000	4.37
Cancellations .....	(499,398)	0.73
Terminated .....	(30,750)	3.12
Exercised .....	<u>(501,897)</u>	0.74
Outstanding at December 31, 2005 .....	739,199	4.22
Granted .....	100,000	1.56
Terminated .....	(1,650)	2.40
Exercised .....	<u>(18,000)</u>	0.73
Outstanding at December 31, 2006 .....	<u>819,549</u>	<u>\$3.97</u>
Options exercisable at December 31, 2006 .....	<u>607,624</u>	<u>\$4.15</u>

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES**

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

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
\$1.35-\$2.40	180,700	6.5	\$1.80	180,700	\$1.80
\$2.88-\$3.00	235,000	1.2	\$2.98	60,000	\$2.93
\$4.35-\$4.91	165,000	8.5	\$4.37	150,000	\$4.37
\$5.20-\$7.12	238,849	4.3	\$6.32	216,924	\$6.29
	<u>819,549</u>	4.7	\$3.97	<u>607,624</u>	\$4.15

The aggregate intrinsic value for the outstanding and exercisable in-the-money options was \$1,100 at December 31, 2006.

A summary of the status of the Company's non-vested options as of December 31, 2006 and changes during the year period is presented below:

<u>Non-vested Options</u>	<u>Number of Shares</u>	<u>Weighted Average Grant-date Fair Value</u>
Outstanding at December 31, 2005 .....	237,187	\$2.88
Granted .....	100,000	\$1.15
Vested .....	(125,262)	\$1.59
Terminated .....	—	—
Exercised .....	—	—
Outstanding at December 31, 2006 .....	<u>211,925</u>	<u>\$2.83</u>

As of December 31, 2006, there was \$122,000 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 1.8 years. No windfall tax benefits were recognized during the years ended December 31, 2006 or 2005.

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES**

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

**11 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 and assets by region for the years ended:

	<u>Domestic</u>	<u>Italian</u>	<u>Eliminations</u>	<u>Total</u>
<b>December 31, 2006:</b>				
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>
<b>December 31, 2005:</b>				
External net sales .....	\$12,896,731	\$ 6,865,076	\$ —	\$19,761,807
Intercompany sales .....	1,090,877	340,293	(1,431,170)	—
Net revenue .....	<u>\$13,987,608</u>	<u>\$ 7,205,369</u>	<u>\$(1,431,170)</u>	<u>\$19,761,807</u>
Income (loss) from operations .....	<u>\$ (686,480)</u>	<u>\$ 970,885</u>	<u>\$ (7,601)</u>	<u>\$ 276,804</u>
Assets .....	<u>\$20,235,634</u>	<u>\$15,667,896</u>	<u>\$ —</u>	<u>\$35,903,530</u>
<b>December 31, 2004:</b>				
External net sales .....	\$12,112,373	\$ 6,821,095	\$ —	\$18,933,468
Intercompany sales .....	835,863	216,829	(1,052,692)	—
Net revenue .....	<u>\$12,948,236</u>	<u>\$ 7,037,924</u>	<u>\$(1,052,692)</u>	<u>\$18,933,468</u>
Loss from operations .....	<u>\$ (224,503)</u>	<u>\$ (226,883)</u>	<u>\$ 136,981</u>	<u>\$ (314,405)</u>
Assets .....	<u>\$20,082,250</u>	<u>\$16,831,975</u>	<u>\$ —</u>	<u>\$36,914,225</u>

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

12 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, 2006, 2005 and 2004 totaled \$513,480, \$558,822 and \$429,803, respectively. The future minimum lease payments under non-cancelable capital leases and their related assets recorded at December 31, 2006 and 2005 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, 2006, were as follows:

2007 .....	\$ 529,351
2008 .....	484,492
2009 .....	382,430
2010 .....	408,270
2011 .....	421,440
Thereafter .....	—
Total minimum lease payments .....	<u>\$2,225,983</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.

13 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. During the years ended December 31, 2005 and 2004, the Company paid IVAX \$617,000 and \$720,000, respectively, for premium payments for the Company's directors and officers insurance coverage and \$60,000 and \$82,000, respectively, for premium payments for the Company's property insurance coverage. During the year ended December 31, 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.

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)**

**14 QUARTERLY FINANCIAL INFORMATION (UNAUDITED)**

The following table summarizes selected quarterly data of the Company for the years ended December 31, 2006 and 2005 (in thousands except per share data):

	<u>First Quarter<sup>(1)</sup></u>	<u>Second Quarter</u>	<u>Third Quarter<sup>(2)(3)</sup></u>	<u>Fourth Quarter</u>	<u>Full Year</u>
<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)
<b>2005</b>					
Net revenue .....	\$5,383	\$5,244	\$ 4,669	\$4,466	\$19,762
Gross profit .....	3,246	3,273	2,519	2,631	11,669
Income (loss) from operations .....	1,876	124	(1,185)	(538)	277
Net income (loss) .....	838	155	(1,100)	(403)	(510)
Basic and diluted net income (loss) per share .....	0.03	0.01	(0.04)	(0.01)	(0.02)

- (1) Includes the effect of the bad debt recovery in 2005 discussed in Note 2, *Summary of Significant Accounting Policies—Accounts Receivable and Allowance for Doubtful Accounts*, and the creation of a full valuation allowance on the Company's foreign net deferred tax assets discussed in Note 7, *Income Taxes*.
- (2) Includes the effect of compensation expense recorded in 2005 as a result of the cancellation of stock options discussed in Note 10, *Shareholders' Equity—Stock Option Plans*.
- (3) Includes the effect of the write-off of certain PARSEC® assets in 2006 as discussed in Note 3, *Write-off of Certain PARSEC® Assets*.

Basic and diluted net income (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 income (loss) per share amounts due to the effects of rounding.

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

Previously reported.

**ITEM 9A. 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, we carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation 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 Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934) are effective in timely alerting them to material information relating to us required to be included in our periodic filings with the Securities and Exchange Commission.

*Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting that occurred during our fourth fiscal quarter of 2006 that would have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

*Requirements of Section 404*

Under the rules and regulations of the Securities and Exchange Commission, we are currently not required to comply with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 until we file our Annual Report on Form 10-K for our fiscal year ending December 31, 2007, so long as we continue to meet the definition of a non-accelerated filer. In our Annual Report on Form 10-K for the year ending December 31, 2007, our management will be required to provide an assessment as to the effectiveness of our internal control over financial reporting, which assessment will be deemed furnished to rather than filed with the Securities and Exchange Commission. 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 assessment and attestation 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 and that our management will be able to certify as to the effectiveness of our internal control over financial reporting, there is no assurance that we will do so. If we are unable to timely comply with Section 404, our management is unable to certify as to the effectiveness of our internal control over financial reporting or our independent registered public accounting firm is unable to attest to that certification, the price of our common stock may be adversely affected. Even if we timely meet the certification and attestation 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.

**ITEM 9B. OTHER INFORMATION**

None.

### PART III

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

Certain information regarding our directors and our executive officers, which is required by Item 10, is set forth below. The remaining information required by Item 10 will be provided by incorporating such remaining information required under such item by reference to the registrant's Proxy Statement to be filed with the Securities and Exchange Commission no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, or, alternatively, by amendment to this Annual Report on Form 10-K under cover of Form 10-K/A no later than the end of such 120-day period.

The following table sets forth information with respect to our directors and our executive officers as of March 26, 2007.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Giorgio D'Urso . . . . .	71	Chief Executive Officer, President and Director
Duane M. Steele . . . . .	56	Vice President - Business Development
Mark S. Deutsch . . . . .	44	Chief Financial Officer and Vice President—Finance
Itzhak Krinsky, Ph.D. . . . .	54	Chairman of the Board of Directors
Mark W. Durand . . . . .	47	Director
Richard S. Egosi . . . . .	44	Director
Fernando L. Fernandez . . . . .	46	Director
Glenn L. Halpryn . . . . .	46	Director
John B. Harley, M.D. . . . .	57	Director
Jose J. Valdes-Fauli . . . . .	55	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, 2007. 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. Giorgio D'Urso, age 71, has served as our President and Chief Executive Officer and as a director since the merger with the pre-merger Diagnostics in 2001 and had served in the same capacities with the pre-merger Diagnostics since 1996. He has served as President and Chief Executive Officer of Diamedix since 1993, President of Delta since 1980, and President of ImmunoVision since 1995. He has over 37 years of diagnostics industry experience. Mr. D'Urso founded Delta, and was its Managing Director from 1980 to 1998. From 1976 to 1980, Mr. D'Urso founded and served as the General Manager of Menarini Diagnostici, Florence, Italy, a division of Menarini S.A.S. Mr. D'Urso also founded and supervised Menarini Diagnosticos S.A. in Spain. From 1974 to 1976, Mr. D'Urso served as the Marketing Manager of the diagnostic division of SmithKline & French S.P.A. in Milan, Italy. From 1969 to 1974, Mr. D'Urso served as the Marketing Manager of Laboratori Travenol S.P.A. in Rome, Italy.

Mr. Duane M. Steele, age 56, has served as our Vice President—Business Development since the merger with the pre-merger Diagnostics in 2001 and had served in the same capacity with the pre-merger Diagnostics since 1996. He joined Diamedix in 1995 and has over 29 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 44, has served as Chief Financial Officer and Vice President—Finance since the merger with the pre-merger Diagnostics in 2001 and had served in the same capacities with the pre-merger Diagnostics since 1996. He has served as the Vice President—Finance of Diamedix since 1993 and has 13 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 54, 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 I. Krinsky, Financial & Investment Consulting in New York City and, from January 1998 until May 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 boards of Can-fite Biopharma Ltd. and Advanced Vision Technology (A.V.T.) Ltd. He 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 47, has served as a director since April 2006. Since 2004, Mr. Durand has served as Chief Financial Officer and Senior Vice President, Finance and Business Development of Teva North America. From 1987 to 2004, 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 the Dartmouth Graduate School Alumni Association. 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. Egesi, age 44, has served as a director since April 2006. Since 1999, Mr. Egesi has served as Senior Vice President and General Counsel of Teva North America, overseeing the legal function for the Teva group of companies in North America. From 1995 to 1999, Mr. Egesi served as Associate General Counsel of Teva. From 1988 to 1995, Mr. Egesi was an attorney in private practice. Mr. Egesi received a J.D. and M.B.A. from Emory University.

Mr. Fernando L. Fernandez, age 46, 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 1991 to 1996 and for a brief period after his service at Whitman Education Group, Inc., 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) Miami, Florida.

Mr. Glenn L. Halpryn, age 46, 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. 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 1984 to 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. Mr. Halpryn is also the acting Chairman of the Board of Directors and acting President of Getting Ready Corporation (public acquisition company).

Dr. John B. Harley, age 57, has served as a director since the merger with the pre-merger 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 Lynn 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 Treasurer of JK Autoimmunity, Inc.

Mr. Jose J. Valdes-Fauli, age 55, has served as a director since December 2002. 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 30 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.

#### **ITEM 11. EXECUTIVE COMPENSATION**

Item 11 will be provided by incorporating the information required under such item by reference to the registrant's Proxy Statement to be filed with the Securities and Exchange Commission no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, or, alternatively, by amendment to this Annual Report on Form 10-K under cover of Form 10-K/A no later than the end of such 120-day period.

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

Item 12 will be provided by incorporating the information required under such item by reference to the registrant's Proxy Statement to be filed with the Securities and Exchange Commission no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, or, alternatively, by amendment to this Annual Report on Form 10-K under cover of Form 10-K/A no later than the end of such 120-day period.

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

Item 13 will be provided by incorporating the information required under such item by reference to the registrant's Proxy Statement to be filed with the Securities and Exchange Commission no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, or, alternatively, by amendment to this Annual Report on Form 10-K under cover of Form 10-K/A no later than the end of such 120-day period.

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

Item 14 will be provided by incorporating the information required under such item by reference to the registrant's Proxy Statement to be filed with the Securities and Exchange Commission no later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, or, alternatively, by amendment to this Annual Report on Form 10-K under cover of Form 10-K/A no later than the end of such 120-day period.

**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:

Reports of Independent Registered Public Accounting Firms

Consolidated Balance Sheets as of December 31, 2006 and 2005

Consolidated Statements of Operations for the years ended December 31, 2006, 2005 and 2004

Consolidated Statements of Shareholders' Equity for the years ended December 31, 2006, 2005 and 2004

Consolidated Statements of Cash Flows for the years ended December 31, 2006, 2005 and 2004

Notes to Consolidated Financial Statements

**(2) Financial Statement Schedules**

The following financial statement schedule is filed as a part of this Annual Report on Form 10-K:

Schedule II      Inventory Reserves for the three years  
ended December 31, 2006

**SCHEDULE II**

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES  
VALUATION AND QUALIFYING ACCOUNTS  
THREE YEARS ENDED DECEMBER 31, 2006  
(In thousands)**

**INVENTORY RESERVES**

<u>Description</u>	<u>Balance at Beginning of Year</u>	<u>Charged to Cost and Expenses</u>	<u>Net Deductions</u>	<u>Other</u>	<u>Balance at End of Year</u>
Year ended December 31, 2004 .....	\$936	143	(647)	4	\$436
Year ended December 31, 2005 .....	\$436	301	(426)	21	\$332
Year ended December 31, 2006 .....	\$332	371	(288)	67	\$421

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

The reports of our independent registered public accounting firms with respect to Schedule II are included in their reports included in Part II, Item 8 of this Annual Report on Form 10-K.

### (3) Exhibits

The following exhibits are either filed as a part of 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	Incorporated by reference to our Form 10-Q filed on August 9, 2002.
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.
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*	Employment Agreement, dated October 1, 1998, between IVAX Diagnostics, Inc. and Giorgio D'Urso	Incorporated by reference to our Form 10-K filed on April 1, 2002.
10.5*	Amendment to Employment Agreement, dated February 24, 2004, between IVAX Diagnostics, Inc. and Giorgio D'Urso	Incorporated by reference to our Form 10-K filed on March 25, 2004.
10.6*	Amendment to Employment Agreement, dated July 13, 2005, between IVAX Diagnostics, Inc. and Giorgio D'Urso	Incorporated by reference to our Form 10-Q filed on August 15, 2005.
10.7	1999 Performance Equity Plan	Incorporated by reference to our Form SB-2 filed on October 6, 1999.
10.8	1999 Stock Option Plan	Incorporated by reference to our Form 10-K filed on April 1, 2002.
10.9	Form of Nonqualified Stock Option Agreement (Employee)	Incorporated by reference to our Form 10-K filed on March 31, 2005.
10.10	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.
23.2	Consent of Independent Registered Public Accounting Firm—Ernst & Young LLP	Filed herewith.

<u>Exhibit Number</u>	<u>Description</u>	<u>Method of Filing</u>
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	**
32.2	Certification of Chief 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.

## SIGNATURES

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

IVAX DIAGNOSTICS, INC.

Dated: March 30, 2007

By:           /s/ GIORGIO D'URSO            
**Giorgio D'Urso,**  
**Chief Executive Officer**  
**and President**

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

<u>Name</u>	<u>Capacity</u>	<u>Date</u>
<u>/s/ GIORGIO D'URSO</u> Giorgio D'Urso	Chief Executive Officer, President and Director (Principal Executive Officer)	March 30, 2007
<u>/s/ MARK S. DEUTSCH</u> Mark S. Deutsch	Chief Financial Officer and Vice President—Finance (Principal Financial Officer) (Principal Accounting Officer)	March 30, 2007
<u>/s/ ITZHAK KRINSKY, PH.D.</u> Itzhak Krinsky, Ph.D.	Chairman of the Board of Directors	March 30, 2007
<u>/s/ MARK W. DURAND</u> Mark W. Durand	Director	March 30, 2007
<u>/s/ RICHARD S. EGOSI</u> Richard S. Egosi	Director	March 30, 2007
<u>/s/ FERNANDO L. FERNANDEZ</u> Fernando L. Fernandez	Director	March 30, 2007
<u>/s/ GLENN L. HALPRYN</u> Glenn L. Halpryn	Director	March 30, 2007
<u>/s/ JOHN B. HARLEY, M.D.</u> John B. Harley, M.D.	Director	March 30, 2007
<u>/s/ JOSE J. VALDES-FAULI</u> Jose J. Valdes-Fauli	Director	March 30, 2007

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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, the risks and uncertainties associated with: our development and commercial release of our new proprietary automated testing system, named the PARSEC® System; the ability of the PARSEC® System to perform as or be available when expected; the impact of the delay in the full commercial release of the PARSEC® System on our international activities associated with the PARSEC® System; our ability to submit our 510(k) application for the PARSEC® System to the Food and Drug Administration when expected or at all; our ability to obtain 510(k) clearance from the Food and Drug Administration for the PARSEC® System when expected or at all; our ability to successfully market the PARSEC® System; our customers' integration of the PARSEC® System into their operations; the impact of sales and reagent rentals of the PARSEC® System on sales and reagent rentals of the Mago® 4, our updated version of the Mago® Plus instrument; our development and commercial release of the Mago® 4; the ability of the Mago® 4 to perform as or be available when expected; our ability to submit our 510(k) application for the Mago® 4 to the Food and Drug Administration when expected or at all; our ability to obtain 510(k) clearance from the Food and Drug Administration for the Mago® 4 when expected or at all; our ability to obtain all necessary regulatory approvals for the Mago® 4 when expected or at all; our ability to successfully market the Mago® 4; our customers' integration of the Mago® 4 into their operations; the impact of sales and reagent rentals of the Mago® 4 on sales and reagent rentals of the PARSEC® System; our ability to successfully receive the transfer of hepatitis technology when expected or at all; if we successfully receive the transfer of hepatitis technology, our ability to manufacture our own hepatitis assays when expected or at all, obtain CE approval for our hepatitis kits when expected or at all, make commercial deliveries of our hepatitis kits when expected or at all or cause our hepatitis assays to be run in conjunction with the PARSEC® System or the Mago® 4; the ability of the PARSEC® System and the Mago® 4 to provide us with significant incremental growth in the future; our ability to achieve improved financial performance or results in the future; 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, 2006 which has been provided as a portion of this annual report. Many of these risks and factors are beyond our control.

**IVAX**  
***Diagnostics, Inc.***

2140 North Miami Avenue  
Miami, Florida 33127  
(305) 324-2300

[www.ivaxdiagnostics.com](http://www.ivaxdiagnostics.com)

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