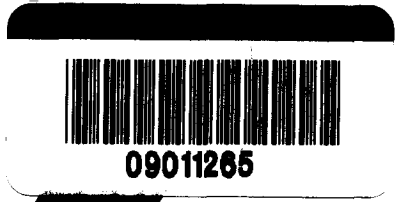


IVAX Diagnostics, Inc.

2008 Annual Report

IVAX Diagnostics, Inc.

May 8, 2009

To Our Stockholders

I became IVAX Diagnostics' CEO and President in January 2009. This is my first opportunity to give you my observations on your company and to share with you some of the exciting initiatives underway at IVAX Diagnostics, all of which are designed to build a stronger, larger and more competitive company.

While IVAX Diagnostics has had a strong foundation and reputation in the industry, the recent change in majority ownership and subsequent change in management has, we believe, been a catalyst for improving upon our operations. On September 2, 2008, a group comprised of Debregeas & Associes Pharma SAS, a company owned by Patrice R. Debregeas, and Paul F. Kennedy, both individually and through Umbria LLC, purchased the 72.3% of our outstanding common stock which was formerly owned by Teva Pharmaceutical Industries, for $14 million in cash, or $0.70 per share. Messrs. Debregeas and Kennedy joined our Board of Directors, and Mr. Debregeas was subsequently appointed as Chairman. Then, after an extensive search for new leadership, I was appointed by the Board of Directors in January 2009 to lead the company.

During 2008 management's emphasis was on maintaining market share and stabilizing our sales and marketing efforts. Our efforts in 2008 were successful, as we ended the year with improved results, which, under current economic conditions, was a monumental achievement. We continued to build upon our customer list of well respected names in healthcare. One large reference laboratory, for example, increased utilization of our kits over 300% in 2008. One of the tests used by that reference laboratory reduces the amount of labor-intensive IFA and microscopic time needed for samples, a mandate of large reference labs to reduce labor intensive steps in the diagnostic process. Demand for our product line is solid. As an example, unit sales for our test for the presence of Cytomegalovirus (CMV) infection in pregnant women increased 27% in 2008 compared to 2007. CMV can cause symptoms/disease similar to mononucleosis and, in pregnant women, it can cause extreme neurological damage to the fetus (cerebral palsy) or fetal loss. In 2008, net revenues increased 4.2% to $20,819,000 compared with $19,976,000 in 2007, and net income for 2008 improved to $196,000 or $0.01 per share, compared with a net loss of $10,434,000, or ($0.38) per share for 2007.

Our 2008 results included a one-time, non-cash write off of $560,000, which had no tax impact, for a portion of our product license for hepatitis technology, and our 2007 results included the tax affected impact of $9,064,000 of one-time charges, which were composed of one-time, non-cash write offs of goodwill and PARSEC System-related assets totaling $7,526,000 and one-time severance-related costs of $1,998,000.

IVAX Diagnostics remains financially sound with approximately $8 million in cash as of the beginning of 2009 and no debt on our balance sheet. We continue to review operations and strive to contain our costs in an effort to increase our efficiencies and drive our margins. While results improved in 2008, your new management team is committed to strengthening our performance in the months and years ahead.

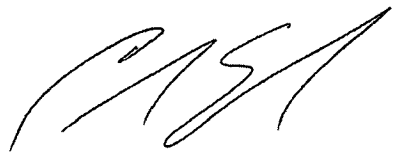
We believe the health care industry will continue to be a growing industry. We expect the importance of IVAX Diagnostics' role in proper disease management will increase with the continued aging of the global population. A shift to personalized medicine is expected to benefit IVAX Diagnostics as well. With the anticipated growth in the industry, we also expect an increased demand for improved

diagnostic capabilities, both in timeliness and accuracy. Our goal is to be at the forefront of delivering leading-edge diagnostic instrumentation and testing.

Our mission is to develop, manufacture, and distribute worldwide, the reagents, test kits, and diagnostic equipment, primarily for autoimmune and infectious diseases, that meet and/or exceed patients' and their physicians' needs for accurate and efficient in vitro diagnosis. We are creating a new mindset at IVAX Diagnostics. Initiatives and research and development efforts are underway to capitalize on our being one of the few fully integrated in vitro diagnostics companies – from protein purification to test kits, automated equipment development, manufacturing and distribution. We believe these initiatives will improve our ability to compete and expand our reach in key countries around the world.

The first focus area for change is in our manufacturing arena, within which we expect to significantly increase our operational efficiency and resulting competitiveness. Additionally, we anticipate increasing the number and reach of our product offerings, both through expanded internal capabilities and external distribution collaborations. Finally, we are working on expanding our current testing platform and disease target areas. Having completed our analysis of our manufacturing operations we now plan to begin a two-year program to modernize and automate certain operations in an effort to improve our competitive position. We expect this program to also provide us additional capacity to enable growth and expand our business. Our management team is committed to excellence and profitability through improved manufacturing and marketing. While the initiatives outlined above are important, communicating to our stockholders and the investment community about our progress along the road to growth is also important. We are initiating a new investor outreach program and our goal is to open communication lines about our strategy, so we can benchmark our progress throughout the years. We have a robust company, with significant cash reserves and no long-term debt. We operate in one of the few growth industries today – health care. We provide an important service to mankind – proper disease diagnosis. Our goal is to be a recognized presence in the industry. We believe the future for IVAX Diagnostics is an exciting one and we look forward to sharing our progress with you along the journey.

Respectfully yours,



Charles R. Struby, Ph.D.
Chief Executive Officer and
President

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, 2008

Commission File Number 1-14798

IVAX Diagnostics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**11-3500746**
(State or other jurisdiction of incorporation or organization)	**(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	**American Stock Exchange**
(Title of class)	**(Name of each exchange on which registered)**

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

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

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

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

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

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

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☒
(Do not check if a smaller reporting company)	

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2008, was approximately $4,880,000 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 27, 2009, there were 27,649,887 shares of common stock outstanding.

Documents Incorporated by Reference:

None.

IVAX Diagnostics, Inc.

Annual Report on Form 10-K
for the year ended December 31, 2008

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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® Plus and Aptus® 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® Plus instrument to include the capability to process ELISA and ImmunoFluorescent Antibody, or IFA, assays simultaneously. Currently, we are only marketing this updated version of the Mago® Plus outside of the United States. We are also developing an upgraded version of the Mago® Plus instrument, named the Mago® 4, which is expected to be able to perform both ELISA and IFA techniques simultaneously, perform positive sample identification and utilize disposable pipette tips. We believe that the Mago® 4 will offer an enhanced automation solution to customers who prefer a more compact, lower-priced instrument with features and benefits similar to many of the other instruments currently offered in the marketplace. It is anticipated that, during 2009, we will only market the Mago® 4 outside of the United States. We intend to seek, but have not yet received, all necessary regulatory approvals for the Mago® 4, and, accordingly, commercial deliveries of the Mago® 4 will await our receipt of such regulatory approvals. In the meantime, we are also developing a variation of the Mago® 4, named the Mago® 4S, which we intend to market in the United States. The Mago® 4S is expected to be able to perform both ELISA and IFA techniques simultaneously and to be operated utilizing a Microsoft Windows user interface and color monitor. We intend to seek all necessary regulatory approvals for the Mago® 4S, and accordingly, commercial deliveries of the Mago® 4S will await our receipt of regulatory approval, which we expect in the first quarter of 2010. We also develop, manufacture and market raw materials, such as antigens used in the production of diagnostic kits.

We previously anticipated that the PARSEC® System, a proprietary instrument system which we were developing and which we believed would enable customers to utilize not only ELISA-based kits, but also other methods such as IFA and chemiluminescent-based assays in the future, would become our primary product. However, as previously disclosed, as a result of continuing delays in the development of the PARSEC® System, we concluded that the Mago® 4 can be developed and brought to market more quickly, using fewer resources and in a more cost-effective manner than completing the development of the PARSEC® System and its proprietary operating system and other software components. Accordingly, during the fourth quarter of 2007, we decided to change our strategic direction to focus on the development of the Mago® 4 as a platform for marketing our kits and to place any further development of the PARSEC® System on hold indefinitely.

Our management reviews financial information, allocates resources and manages the business as two segments defined by geographic region. One segment—the domestic region—contains our subsidiaries located in

the United States and corporate operations. Our other segment—the Italian region—contains our subsidiary located in Italy. For additional information about our two segments, see Note 13 to our Consolidated Financial Statements.

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

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

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

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

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

Controlling Stockholder. On July 25, 2005, IVAX, which then owned approximately 72.3% of the outstanding shares of our common stock, entered into a definitive agreement and plan of merger with Teva 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, indirectly through its wholly-owned IVAX subsidiary, owned approximately 72.3% of the outstanding shares of our common stock.

On September 2, 2008, a group comprised of Debregeas & Associes Pharma SAS, a company wholly-owned by Patrice R. Debregeas and members of his family, Paul F. Kennedy and Umbria LLC, a company wholly-owned by Mr. Kennedy, purchased from Teva all of the approximately 72.3% of the outstanding shares of our common stock owned by Teva, indirectly through its wholly-owned IVAX, for an aggregate purchase price of $14,000,000, or $0.70 per share. For purposes of this Annual Report on Form 10-K, Debregeas & Associes Pharma SAS, Patrice R. Debregeas, Paul F. Kennedy and Umbria LLC are collectively known as the Debregeas-Kennedy Group.

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 $42.0 billion in 2007 and estimated to grow at a rate of 6% annually over the next five years. Of this total $42.0 billion market, the North American market is estimated by industry analysts to represent approximately 44% of the total world market for in vitro diagnostics. We have focused our efforts on the niche market for autoimmune and infectious disease immunoassay products. Our ELISA autoimmune product line consists of approximately 20 test kits that the FDA has cleared. These include test kits for screening antinuclear antibodies and specific tests to measure antibodies to dsDNA, SSA, SSB, Sm, Sm/RNP, Scl 70, Jo-1, Rheumatoid Factor, MPO, PR-3, TPO, TG, and others. These products are used for the diagnosis and monitoring of autoimmune diseases, including Systemic Lupus Erythematosus, or SLE, Rheumatoid Arthritis, Mixed Connective Tissue Disease, Sjogren's Syndrome, Scleroderma, and Dermatopolymyositis. Our infectious disease product line, together with kits obtained from third party companies, includes approximately 30 kits that the FDA has cleared, including Toxoplasma IgG, Toxoplasma IgM, Rubella IgG, Rubella IgM, Cytomegalovirus, or CMV, IgG, CMV IgM, Herpes Simplex Virus, or HSV, IgG, HSV IgM, Measles, Varicella Zoster Virus, or VZV, Lyme Disease, H. pylori, Mumps, six different Epstein-Barr Virus, or EBV, kits and others. In international markets, this line of autoimmune and infectious disease products is supplemented by additional products that are obtained from third party companies. We also have access from a third party company to market and sell in Europe and the United States a line of oral fluid and urinary homogeneous enzyme immunoassay test products for the detection of drugs of abuse. These oral fluid and urinary homogeneous enzyme immunoassay test products include the detection of Ecstasy, Oxycodone, Methadone, Cocaine Metabolite, Amphetamines, Opiate, Methadone Metabolite, Cotinine and Ethyl Alcohol.

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

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

In an effort to supplement our proprietary instruments offered to those customers that require instrumentation features not available on our Mago® Plus or Aptus® systems, we have entered into an agreement with Dynex Technologies pursuant to which we can promote their DSX™ and DS2™ instrument systems in conjunction with our test kits on a worldwide basis.

Research and Development. We devote substantial resources for research and development. For the years ended December 31, 2008 and 2007, we incurred $1.8 million and $2.2 million, respectively, for research and development activities.

As a result of our decision during the fourth quarter of 2007 to change our strategic direction to focus on the development of the Mago® 4 as a platform for marketing our kits and to place any further development of the PARSEC® System on hold indefinitely, our research and development efforts, which were previously targeted primarily towards the development of the PARSEC® System, are currently targeted primarily towards the development of the Mago® 4 and Mago® 4S. While there is no assurance that we will be successful, we are seeking to expand the test kits menu we offer in the autoimmune and infectious disease testing sectors and considering moving into additional diagnostic test sectors such as HIV and hepatitis. In September 2004, we signed a license agreement with an Italian diagnostics company that allows us access to its technology for manufacturing certain hepatitis products. This agreement is expected to enable us to become competitive in markets outside of the United States by providing us with the technology that, over time, would allow us to internally manufacture many of our own hepatitis products with the "CE Marking," as well as internally manufacture our own raw materials for these hepatitis products. As a result of our change in strategic direction described above, the timeframe during which we had expected to begin marketing hepatitis test kits manufactured at our Italian facilities was delayed. Additionally, following the results of the recently concluded inspection by the applicable notifying body required to obtain "CE Marking," we believe that the product launch of our hepatitis test kits will be further delayed until the first quarter of 2010, in large part, as a result of a backlog of activity and limited available resources at the applicable notifying body.

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

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

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

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

Competition. We compete on a worldwide basis and there are numerous competitors in the specific market sectors in which we offer our products. These competitors range from major pharmaceutical companies to development stage diagnostic companies. Many of these companies, such as Siemens Medical Solutions, are much larger and have significantly greater financial, technical, manufacturing, sales and marketing resources than us. According to industry analysts, 16 companies account for an approximately 86% market share of the total in vitro diagnostics market.

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., The Binding Site Limited 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, 2008, we had approximately 106 full time employees, of whom 13 were managerial, 48 were technical and manufacturing, 9 were administrative and 36 were sales and marketing.

Intellectual Property. The technology associated with the design and manufacture of the Mago® 4, Mago® 4S, 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 derivations of and upgrades to the Mago® will become our primary platforms for marketing our kits.

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

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

may be subject to special controls and/or performance standards and are usually subject to pre-market notification. Class III devices typically require Pre-Market Approvals by the FDA to ensure their safety and effectiveness. All of our products are classified as Class I or II devices.

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

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

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

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

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

Our employment relations in Italy are governed by numerous regulatory and contractual requirements, including national collective labor agreements and individual employer labor agreements. These arrangements

address a number of specific issues affecting our working conditions including hiring, work time, wages and benefits and termination of employment. We must make significant payments in order to comply with these requirements.

Available Information. We file various reports with the Securities and Exchange Commission. We make available, free of charge, through our Internet web site, these reports, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as soon as reasonably practicable after such documents are electronically filed with or furnished to the Securities and Exchange Commission. Our Internet web site is www.ivaxdiagnostics.com. Information contained in our Internet web site is not part of this Annual Report on Form 10-K and shall not be incorporated by reference herein.

ITEM 1A. RISK FACTORS

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

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

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

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

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

Our strategic initiatives, including our automation strategy, our development and commercial release of the upgraded versions of our existing Mago® Plus instrument and the expansion of our menu of test kits, may not be successful.

Our test kits are designed to be performed either manually or in an automated format. We also design and manufacture our laboratory instruments to perform tests in a fully-automated mode. In furtherance of our automation strategy, we are developing an upgraded version of our existing Mago® Plus instrument, which is named the Mago® 4. It is anticipated that, during 2009, we will only market the Mago® 4 outside of the United States. We intend to seek, but have not yet received, all necessary regulatory approvals for the Mago® 4, and, accordingly, commercial deliveries of the Mago® 4 will await our receipt of such regulatory approvals. In the meantime, we are also developing a variation of the Mago® 4, named the Mago® 4S, which we intend to market in the United States. We intend to seek all necessary regulatory approvals for the Mago® 4S, and, accordingly, commercial deliveries of the Mago® 4S will await our receipt of regulatory approval. There can be no assurance that we will be able to obtain all necessary regulatory approvals for the Mago® 4 or Mago® 4S when anticipated,

or at all. Additionally, there can be no assurance that our financial condition, operating results or cash flows or the judgments and estimates we have made with respect to our inventory, property and equipment, equipment on lease, goodwill and product intangibles will not be impacted by the anticipated timing of the commercial release of the Mago® 4 or Mago® 4S.

We expect that derivations of and upgrades to the Mago® will become our primary platforms for marketing our kits. However, the development and marketing of new or enhanced products, including, without limitation, the Mago® 4 and Mago® 4S, is a complex and uncertain process. Accordingly, we cannot be certain that:

- the Mago® 4 or Mago® 4S will be available when expected, or at all,
- the Mago® 4 or Mago® 4S will perform as expected,
- the derivations of or upgrades to the Mago® will become our primary platforms for marketing our kits,
- the Mago® 4 or Mago® 4S will enable us to expand the menu of test kits we offer,
- the Mago® 4 or Mago® 4S will be a source of revenue growth for us,
- we will receive financial benefits or achieve improved operating results after the commercial release of the Mago® 4 or Mago® 4S,
- we will be successful in the marketing of the Mago® 4 or Mago® 4S, or
- customers will integrate the Mago® 4 or Mago® 4S into their operations as readily as expected.

Additionally, in an effort to expand the menu of test kits we offer, in September 2004, we entered into a license agreement with an Italian diagnostics company that allows us access to its technology for manufacturing certain hepatitis products. We expect this agreement to enable us to become competitive in markets outside of the United States by providing us with technology that, over time, would allow us to internally manufacture many of our own hepatitis products with the "CE Marking," as well as internally manufacture our own raw materials for those hepatitis products. However, there remains a risk that we will not be able to obtain product technology that would enable us to manufacture hepatitis products or, if we obtain such product technology, that we will not be able to manufacture hepatitis products or obtain regulatory approval for these products. As a result of our decision during the fourth quarter of 2007 to change our strategic direction to focus on the development of the Mago® 4 as a platform for marketing our kits and to place any further development of the PARSEC® System on hold indefinitely, the timeframe during which we had expected to begin marketing hepatitis test kits manufactured at our Italian facilities was delayed. Additionally, following the results of the recently concluded inspection by the applicable notifying body required to obtain "CE Marking," the product launch of our hepatitis test kits has been further delayed. While we believe that we will be able to bring these hepatitis kits to market, if the progress of our efforts to begin marketing these kits is further adversely impacted, then we may find it necessary to further delay the product launch of our hepatitis test kits.

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

Our implementation of our new strategic direction, which includes focusing on the development of the Mago® 4 and Mago® 4S as platforms for marketing our kits, could adversely affect our business, prospects, operating results, financial condition or cash flows.

We made a strategic direction in the fourth quarter of 2007 to focus on the development of the Mago® 4 as a platform for marketing our kits and placing any further development of the PARSEC® System on hold indefinitely. There can be no assurance that we will successfully implement this change in strategic direction. Additionally, the timeframe during which we had expected to begin marketing hepatitis test kits to be manufactured at our Italian facilities pursuant to a technology license was delayed. Following the results of the recently concluded inspection by the applicable notifying body required to obtain "CE Marking," which has further delayed our product launch, we determined that the carrying amount of the hepatitis technology product

license was in excess of its fair value and recorded a non-cash impairment charge to operations totaling $0.6 million, reducing the value of our hepatitis technology product license to $0.7 million as of December 31, 2008, from $1.2 million as of December 31, 2007. At December 31, 2008, we had approximately $0.7 million of intangible assets and approximately $0.1 million of accrued payables relating to the hepatitis technology product license. The most recent delays in our ability to receive "CE Marking" in the European Union on these hepatitis test kits was due, in large part, to the ongoing workload and limited resources of the applicable notifying body reviewing our regulatory submission. We believe that this most recent delay has had a negative impact on our ability to timely introduce our new hepatitis test kits and achieve our originally anticipated sales levels of these test kits. While we believe we will be able to bring hepatitis test kits to market, if the progress of our efforts to begin marketing hepatitis test kits is further adversely impacted, then we could be required to record an additional impairment charge with respect to all or a portion of the remaining $0.7 million intangible product license of hepatitis technology asset and pay all or a portion of these accrued payables. Any of these factors could materially and adversely affect our business, prospects, operating results, financial condition or cash flows.

Our future success depends on the development of new markets.

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

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

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

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

There are inherent uncertainties involved in the estimates and judgments we make regarding our inventory and changes in these estimates and judgments could have a material adverse effect on our financial condition, operating results and cash flows. As of December 31, 2008, our total inventories included approximately $0.2 million in Mago® 4 instrumentation and instrument components and $0.2 million of inventory relating to our hepatitis products which are currently pending regulatory approval. There can be no assurance that we will not have to make or change judgments and estimates regarding our inventory as a result of any delay of the commercial launch of, future design changes to, the development of improved instrument versions of or future demand for, either the Mago® 4, Mago® 4S or our hepatitis products, nor can there be assurance that such judgments and estimates, or changes in judgments and estimates, will not adversely impact our financial condition and operating results.

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

From time to time, we purchase or make significant quantities of parts and products prior to the date on which we receive final regulatory clearance or begin our full commercial marketing. As of December 31, 2008, our total inventories included approximately $0.2 million in Mago® 4 instrumentation and instrument components and $0.2 million of inventory relating to our hepatitis products which are currently pending regulatory approval. The production of pre-launch inventories for our products, including, without limitation, the

Mago® 4, Mago® 4S and our hepatitis products, involves the risks, among others, that the parts and products may not be approved for commercial marketing by the applicable regulatory authorities on a timely basis, or at all, that the launch of the products may be significantly postponed or, as a result of the discontinuation of such products or otherwise, cancelled, or that we may not be able to find alternative uses for such inventory. If any of these events were to occur, then we may be required to reassess the net realizable value of the related inventory and could, in such case, incur a charge to write down the value of such inventory, which would adversely affect our operating results in the period in which the determination or charge is or was made.

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

We have sought to differentiate ourselves from our competitors through our proprietary instrument systems. While some of our competitors offer proprietary instruments, other competitors use third parties to manufacture these instruments for them. We manufacture our Mago® Plus and Aptus® instruments, and are currently developing and plan to manufacture the Mago® 4 and Mago® 4S, 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 2008, we incurred approximately $1.8 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 through Delta's sales representatives and independent agents who are restricted from selling competing products. There is no assurance that third party distributors or independent sales personnel will achieve acceptable levels of sales or that, if any of our existing arrangements expire or terminate, we will be able to replace any distributors or sales personnel on terms advantageous to us, or at all. Further, there is no assurance that we will be able to expand our distribution network by adding additional distributors or sales personnel. If third party distributors or independent sales personnel cease to promote our products, or if we are unable to make acceptable arrangements with distributors or sales personnel in other markets, our business, prospects, operating results or financial condition could be materially adversely affected.

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

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

We also rely on trade secrets, unpatented proprietary know-how and continuing technological innovation. We use confidentiality agreements with licensees, suppliers, employees and consultants to protect our trade

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

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

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

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

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

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

- product returns,
- allowances for doubtful accounts,
- inventories and related reserves,
- goodwill and other intangible assets,

- income and other tax accruals,
- deferred tax asset valuation allowances,
- discounts and allowances,
- stock based compensation,
- 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.

Following the results of the recently concluded inspection by the applicable notifying body required to obtain "CE Marking," which has further delayed our product launch, we determined that the carrying amount of the hepatitis technology product license was in excess of its fair value and recorded a non-cash impairment charge to operations totaling $0.6 million, reducing the value of our hepatitis technology product license to $0.7 million as of December 31, 2008, from $1.2 million as of December 31, 2007. While we believe that we will be able to bring these hepatitis kits to market, if the progress of our efforts to begin marketing these kits is further adversely impacted, then we may be required to record an additional impairment charge with respect to all or a portion of the remaining $0.7 million intangible product license of hepatitis technology asset.

During the third quarter of 2007, we determined, based principally upon the recent decline in our current market capitalization to less than its June 30, 2007 book value for the preceding seven weeks prior to the end of the third quarter of 2007, as well as our decision to change our strategic direction to place any further development of the PARSEC® System on hold indefinitely, there was sufficient indication to require us to assess, in accordance with SFAS No. 142, whether any portion of our goodwill balance, which is recorded in both ImmunoVision and Delta, was impaired. Based primarily upon our estimate of forecasted discounted cash flows for each of these subsidiaries and our market capitalization, we determined that the carrying amount of the goodwill at each of Delta and ImmunoVision was in excess of its respective fair value. We concluded that all $4.7 million of the goodwill recorded at Delta and $1.2 million of the $2.1 million of goodwill recorded at ImmunoVision was impaired. As a result, we recorded a noncash goodwill impairment charge to operations totaling $5.9 million during the third quarter of 2007. No impairment charge was recorded for the goodwill at ImmunoVision for 2008. A continued decline in our market capitalization could require us to record additional impairment charges in future periods for the remaining goodwill for ImmunoVision, which would have a material adverse effect on our financial position and operating results.

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

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

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

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

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

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

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

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

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

Compliance with governmental regulation is critical to our business.

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

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

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

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

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

Delta, our wholly-owned subsidiary, is located in Italy. Our employment relations in Italy are governed by numerous regulatory and contractual requirements, including, among other things, national collective labor agreements and individual employer labor agreements. These arrangements address a number of specific issues affecting our working conditions, including, without limitation, hiring, work time, wages and benefits and termination of employment. We must make significant payments in order to comply with these requirements. The cost of complying with these requirements may materially adversely affect our business, prospects, operating results or financial condition. Additionally, Delta must comply with minimum capital requirements established by Italian law. From time to time, we may utilize cash to assist Delta in maintaining its compliance with these capital requirements. There can be no assurance that Delta will be able to maintain its compliance with these capital requirements with or without our cash assistance. Under certain circumstances, during the time when Delta is utilizing cash assistance that we provide, the amount of such cash assistance may not be available for our use in other portions of our business. Furthermore, any cash assistance that we provide to Delta may not be repaid or distributed to us when expected, or at all. Any of these risks may adversely affect our liquidity or financial condition.

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

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

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

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

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

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

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

For the year ended December 31, 2008, we recorded net revenues of $20.8 million and net income of $0.2 million. For the year ended December 31, 2007, we recorded net revenues of $20.0 million and net loss of $10.4 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 of 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, 2008 and 2007, our accounts receivable were $6.1 million and $7.3 million, respectively, and our allowance for doubtful accounts was $0.4 million and $1.1 million, respectively. As of December 31, 2008 and 2007, $4.1 million and $5.2 million, respectively, of our

accounts receivable were due in Italy, and $0.2 million and $0.8 million, respectively, of our allowance for doubtful accounts related to Italian accounts receivable. As of December 31, 2008 and 2007, 50.9% and 58.3%, respectively, of our net accounts receivable were due from hospitals and laboratories controlled by the Italian government. Accordingly, we are subject to credit risk if the Italian government does not, or is not able to, pay amounts owed to us.

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

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

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

We have a significant wholly-owned subsidiary, Delta, located in Italy. For the years ended December 31, 2008 and 2007, Delta represented 31.5% and 31.3%, 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, 2008 and 2007, 31.5% and 31.3%, respectively, of our net revenues were generated in currencies other than the United States dollar. Fluctuations in the value of foreign currencies relative to the United States dollar affect our operating results. For instance, if the United States dollar strengthens

relative to foreign currency, then our earnings generated in foreign currency will, in effect, decrease when converted into United States dollars, which could have a material and adverse effect on our operating results and cash flows. We do not use financial derivatives to hedge exchange rate fluctuations.

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

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

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

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

In this Annual Report on Form 10-K, our management has provided an assessment as to the effectiveness of our internal control over financial reporting. However, because we meet the definition of a non-accelerated filer, under the current rules and regulations of the Securities and Exchange Commission, our management's assessment is furnished to, rather than filed with, the Securities and Exchange Commission, and our independent registered public accounting firm was not required to provide, and has not provided, in this Annual Report on Form 10-K an attestation as to our management's assessment. In our Annual Report on Form 10-K for the year ending December 31, 2009 and for each fiscal year thereafter, our management will be required to provide an assessment as to the effectiveness of our internal control over financial reporting and our independent registered public accounting firm will be required to provide an attestation as to our management's assessment, which assessment and attestation will be filed with the Securities and Exchange Commission. The processes required by Section 404 are relatively new to us. Accordingly, we may encounter problems or delays in completing our obligations and receiving an unqualified report on our internal control over financial reporting by our independent registered public accounting firm.

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

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

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

Patrice R. Debregeas and Paul F. Kennedy, together, may be deemed to control our company.

Patrice R. Debregeas and Paul F. Kennedy, collectively, may be deemed to beneficially own 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, Messrs. Debregeas and Kennedy, acting together and without the consent of any of our other stockholders, can approve actions that require stockholder approval and elect directors acceptable to them based on their share ownership.

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

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

Our common 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 common stock to be volatile.

Our common stock has been listed and traded on the American Stock Exchange since March 15, 2001. Because the Debregeas-Kennedy Group collectively owns approximately 72.3% of the issued and outstanding shares of our common stock, we have a limited non-affiliate market capitalization. As a result, our common stock has a limited trading volume, which makes it more difficult for our stockholders to sell their shares.

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

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

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

Our board of directors is authorized to issue up to 5,000,000 shares of preferred stock without any further action on the part of our stockholders. Currently, we have no shares of preferred stock outstanding. In the event that we issue preferred stock in the future that has preference over the common stock with respect to payment of dividends or upon our liquidation, dissolution or winding up, the rights of holders of shares of our common stock

may be adversely affected. In addition, the ability of our board of directors to issue shares of preferred stock without any further action on the part of our stockholders may impede a takeover of us and may prevent a transaction that is favorable to our stockholders.

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

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

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

- our ability to successfully promote the DSX™ and DS2™ instrument systems from Dynex Technologies in conjunction with our test kits on a worldwide basis;
- our ability to expand the menu of test kits that we offer to include other complementary infectious disease or autoimmune testing sectors or otherwise;
- the response of our current customer base to an expansion of our menu of test kits;
- our ability to achieve organic growth;
- our ability to identify or consummate acquisitions of businesses or products;
- our ability to integrate acquired businesses or products;
- our ability to enhance our position in laboratory automation;
- our ability to expand our product offerings and/or market reach or become a leader in the diagnostics industry;
- constantly changing, and our compliance with, governmental regulation;
- the impact of our adoption or implementation of new accounting statements and pronouncements on our financial condition and operating results;
- our limited operating revenues and history of primarily operational losses;
- our ability to collect our accounts receivable and the impact of making or changing judgments and estimates regarding our allowances for doubtful accounts on our financial condition and operating results;
- our ability to utilize our net operating losses and the impact of making or changing judgments and estimates regarding our deferred tax liabilities and our valuation allowances and reserves against our deferred tax assets on our financial condition and operating results;
- the impact of making or changing judgments and estimates regarding our goodwill, including the remaining goodwill recorded at ImmunoVision, and other intangible assets, such as our hepatitis technology product license, on our financial condition and operating results;
- our ability to achieve cost advantages from our own manufacture of instrument systems, reagents and test kits;
- our ability to grow beyond the autoimmune and infectious disease markets and to expand into additional diagnostic test sectors;
- our ability to obtain product technology from the Italian diagnostics company that would enable us to manufacture our own hepatitis products;
- our ability to receive authorization for "CE Marking" for our own hepatitis products in the European Union when expected, or at all;
- our ability to internally manufacture our own hepatitis products and raw materials for these products and to become competitive in markets outside of the United States;
- our ability to derive revenue from our manufacture and sale of our own hepatitis products;
- the impact of the anticipated timing of the regulatory approval and commercial launch of our own hepatitis products on the judgments and estimates we have made with respect to our inventory and product intangibles and on our financial condition, operating results and cash flows;
- our agreements with 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 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 Delta 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 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 Patrice R. Debregeas and Paul F. Kennedy;
- conflicts of interest with the Debregeas-Kennedy Group 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, 2008.

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 27, 2009, 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 2008 and 2007, as reported by the American Stock Exchange:

2008	High	Low
Fourth Quarter	$0.68	$0.35
Third Quarter	1.00	0.01
Second Quarter	0.81	0.42
First Quarter	0.69	0.31
2007		
Fourth Quarter	$0.71	$0.45
Third Quarter	1.09	0.60
Second Quarter	1.29	0.88
First Quarter	1.47	0.95

We did not declare or pay cash dividends on our common stock during 2008 or 2007, and we do not intend to pay any cash dividends in the foreseeable future.

ITEM 6. SELECTED FINANCIAL DATA

Not required.

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

The following discussion and analysis should be read in conjunction with our Consolidated Financial Statements and the related Notes to Consolidated Financial Statements on pages 38 to 63 of this Annual Report on Form 10-K.

OVERVIEW

We are the parent corporation of the following three subsidiaries:

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

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

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

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

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

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

MAJORITY STOCKHOLDER

On July 25, 2005, IVAX, which then owned approximately 72.3% of the outstanding shares of our common stock, entered into a definitive agreement and plan of merger with Teva providing for IVAX to be merged into a wholly-owned subsidiary of Teva. On January 26, 2006, the merger was consummated and IVAX became a wholly-owned subsidiary of Teva for an aggregate purchase price of approximately $3.8 billion in cash and

123 million Teva ADRs. The transaction was reported to be valued, for accounting purposes, at $7.9 billion, based on the value of the Teva ADRs during the five trading day period commencing two trading days before the date of the definitive agreement and plan of merger. As a result of the merger, Teva, indirectly through its IVAX subsidiary, owned approximately 72.3% of the outstanding shares of our common stock.

On September 2, 2008, a group comprised of Debregeas & Associes Pharma SAS, a company wholly-owned by Patrice R. Debregeas and members of his family, Paul F. Kennedy and Umbria LLC, a company wholly-owned by Mr. Kennedy, purchased from Teva all of the approximately 72.3% of the outstanding shares of our common stock owned by Teva, indirectly through its wholly-owned IVAX subsidiary, for an aggregate purchase price of $14,000,000, or $0.70 per share. For purposes of this Annual Report on Form 10-K, Debregeas & Associes Pharma SAS, Patrice R. Debregeas, Paul F. Kennedy and Umbria LLC are collectively known as the Debregeas-Kennedy Group.

RESULTS OF OPERATIONS

YEAR ENDED DECEMBER 31, 2008 COMPARED TO THE YEAR ENDED DECEMBER 31, 2007

OVERVIEW

Net income totaled $196,000 in 2008 compared to a net loss of $10,434,000 in 2007. Operating loss was $243,000 in 2008 compared to an operating loss of $11,318,000 in 2007. Net income and income from operations improved significantly during 2008 compared to 2007 due to one-time charges recorded in 2007, improvements in revenue and gross profit, and reductions in operating expenses. The results of 2008 included a write-off of a portion of our product license of hepatitis technology of $560,000. The results for 2007 included a write-off of goodwill of $5,852,000, which consisted of the write-off of the entire balance of goodwill related to our Italian operations of $4,672,000 and $1,180,000 of the $2,050,000 of the goodwill recorded at ImmunoVision, a member of our domestic segment. The results for 2007 also included a write-off of PARSEC® System related assets totaling $1,674,000 and severance costs of $1,998,000 included in general and administrative expenses that were incurred in connection with management and other personnel changes. Net revenues increased $843,000 to $20,819,000 in 2008 from $19,976,000 in 2007, due to increases in domestic net revenues of $535,000 primarily as a result of increases in diagnostic kit sales to instrumentation customers and increased instrumentation sales, and increases in Italian net revenues as a result of the increase in revenue of $478,000 resulting from fluctuations of the United States dollar relative to the Euro. As measured in Euros, Italian net revenues declined by 2.7% compared to 2007. Gross profit increased $854,000 to $12,431,000, or 59.7% of net revenues, in 2008 from $11,577,000, or 58.0% of net revenues, in 2007. Operating expenses decreased in all categories in 2008 compared to 2007, particularly in Italy, which included the benefits of the effect of management and other personnel reductions, the impact of our decision during the fourth quarter of 2007 to place any further development of the PARSEC® System on hold indefinitely and a reduction in bad debt expense. Total other income decreased slightly in 2008 compared to 2007, with a reduction of interest income offset by an increase in other income due to greater foreign currency gains. Additionally, we had a net tax expense of $106,000 in 2008 compared to a net tax benefit of $329,000 in 2007. This difference was due to a 2007 deferred tax benefit resulting from the required adjustment of our deferred tax liability related to tax deductible goodwill recorded as a result of the goodwill impairment charge at ImmuoVision.

NET REVENUES AND GROSS PROFIT

	2008	2007	Period over Period Increase (Decrease)
Net Revenues			
Domestic	$14,262,000	$13,727,000	$535,000
Italian	6,557,000	6,249,000	308,000
Total	20,819,000	19,976,000	843,000
Cost of Sales	8,388,000	8,399,000	(11,000)
Gross Profit	$12,431,000	$11,577,000	$854,000
% of Total Net Revenues	59.7%	58.0%	

Net revenues in 2008 increased $843,000, or 4.2%, from 2007. This increase was comprised of increases in net revenues from domestic operations of $535,000 and net revenues from Italian operations of $308,000. Domestic net revenues in 2008 increased 3.9% compared to 2007, primarily due to increases in diagnostic kit sales to instrumentation customers and increased instrumentation sales. The 4.9% increase in net revenues from Italian operations includes the effect of an increase in revenue of $478,000 due to currency fluctuations of the United States dollar relative to the Euro as further discussed in "Currency Fluctuations" below. As measured in Euros, Italian net revenues declined by 2.7% compared to 2007 due principally to a decrease in sales volumes to customers within Italy, partially offset by an increase in sales from Italy to our international distributors. Gross profit in 2008 increased $854,000, or 7.4%, from the prior year primarily as a result of the increase in net revenues, including the effect of exchange rate fluctuations, described above. The principal factors in the increase in gross profit as a percentage of net revenues to 59.7% in 2008 from 58.0% in 2007 were lower labor costs and exchange rate benefits and, to a lesser extent, improved gross margins on domestic reagent sales.

OPERATING EXPENSES

	2008	% of Revenue	2007	% of Revenue	Period over Period Increase (Decrease)
Selling Expenses					
Domestic	$ 3,111,000	14.9%	$ 3,123,000	15.6%	$ (12,000)
Italian	1,822,000	8.8%	2,363,000	11.9%	(541,000)
Total	4,933,000	23.7%	5,486,000	27.5%	(553,000)
General and Administrative	5,364,000	25.8%	7,730,000	38.7%	(2,366,000)
Research and Development	1,817,000	8.7%	2,152,000	10.8%	(335,000)
Impairment of Product License and Goodwill	560,000	2.7%	5,852,000	29.3%	(5,292,000)
Write-off of PARSEC® Related Assets	—	N/A	1,674,000	8.4%	(1,674,000)
Total Operating Expenses	$12,674,000	60.9%	$22,894,000	114.6%	$(10,220,000)

The most significant variations in operating expenses occurred as a result of two non-cash charges recorded during 2007, the largest of which was a goodwill impairment charge of $5,852,000. The determination to analyze our recorded goodwill balance for impairment was based principally upon the decline in our market capitalization to less than our June 30, 2007 book value for the preceding seven weeks prior to the end of the third quarter, as well as the decision to change our strategic direction and to place any further development of the PARSEC® System on hold indefinitely. Based primarily upon our estimate of forecasted discounted cash flows and our market capitalization, we determined that the carrying amount of the goodwill at our Italian subsidiary, Delta Biologicals, and at ImmunoVision, a member of our domestic segment, was in excess of its respective fair value. On completion of the second step of the analysis of our goodwill balance, we concluded that all $4,672,000 of the goodwill recorded at Delta Biologicals and $1,180,000 of the $2,050,000 of goodwill recorded

at ImmunoVision was impaired. As a result, we recorded a non-cash goodwill impairment charge to operations totaling $5,852,000 during 2007. We did not record a goodwill impairment charge during 2008.

The other non-cash charge during 2007 was a write-off of PARSEC® System related assets included in inventory, property and equipment, equipment on lease and other current assets totaling $1,674,000 as a result of our decision during the fourth quarter of 2007 to change our strategic direction to focus on the development of the new Mago® 4 instrument as a platform for marketing our test kits and to place any further development of the PARSEC® System on hold indefinitely. We did not record a write-off of PARSEC® System related assets during 2008.

In 2008, we recorded a non-cash charge of $560,000 relating to the partial impairment of our product license of hepatitis technology. Following the results of the recently concluded inspection by the applicable notifying body required for us to obtain "CE Marking," and considering the impact of the current global economic conditions, we revised our assumptions supporting the computation of the fair value of the license to reflect the further delay in product launch and the possibility of a decrease in projected market share as a result of this delay. Based upon this methodology, and utilizing significant assumptions in the income approach used to determine fair value, we recorded a non-cash product license impairment charge to operations totaling $560,000 during 2008. We did not record a product license impairment charge during 2007.

All other categories of operating expenses also declined in 2008 compared to 2007. General and administrative expenses decreased $2,366,000 in 2008 compared to 2007 principally due to accrued severance costs of $1,998,000 as a result of anticipated costs associated with management and other personnel changes that occurred, or were being negotiated during, 2007. Included in this amount is the effect of a separation agreement and general release negotiated with Giorgio D'Urso in connection with his resignation, effective January 10, 2008, as our President and Chief Executive Officer and as a member of our Board of Directors. Pursuant to this separation agreement, we paid Mr. D'Urso a one-time lump-sum payment of $495,000 and terminated his then existing employment agreement that provided for Mr. D'Urso to serve as our President and Chief Executive Officer until February 24, 2010 and to receive a minimum annual base salary of $348,519. The remaining severance costs principally include estimated costs in connection with the terminations of selected employees of Delta Biologicals, our Italian subsidiary. The decrease in general and administrative expenses was also the result of significant bad debt recoveries, particularly in Italy, as well as lower professional fees. This decrease in general and administrative expenses was partially offset by an increase in compensation costs and legal fees relating to the acquisition by the Debregeas-Kennedy Group of the approximately 72.3% of our outstanding shares of our common stock previously owned by Teva.

Selling expenses decreased $553,000 in 2008 compared to 2007. Selling expenses amounted to 23.7% of net revenues in 2008 compared to 27.5% of net revenues in 2007. The decrease in Italian selling expense of $541,000 was primarily as a result of a reduction in labor costs. As measured in Euros, Italian selling expense decreased 491,000 Euro, or 28.5%, principally due to reduced headcount.

Research and development expenses decreased $335,000 in 2008 compared to 2007. As measured in Euros, Italian research and development expenses decreased to 773,000 Euro in 2008 from 1,128,000 Euro in 2007 primarily as a result of a decline in labor, professional fees and associated operating costs resulting from our decision during the fourth quarter of 2007 to place any further development of the PARSEC® System on hold indefinitely and to focus on the development of the Mago® 4 as a platform for marketing our test kits. Additionally, the decrease in Italian research and development expenses was partially offset by comparatively smaller increases in hepatitis product development costs in Italy. Domestic research and development expenses were relatively unchanged from 2007 to 2008. Domestic research and development expenses during 2008 included expenses associated with the validation of our test kits on the DSX™ and DS2™ instrument systems from Dynex Technologies that we have begun to promote in conjunction with our test kits. 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.

LOSS FROM OPERATIONS

Loss from operations totaled $243,000 in 2008 compared to a loss from operations of $11,318,000 in 2007. Loss from operations in 2008 was composed of a $61,000 loss from domestic operations, including the $560,000 charge for the impairment of our product license of hepatitis technology, and a loss from Italian operations of $174,000. The loss from operations in 2007 was composed of a loss from Italian operations of $9,304,000, which included charges of $4,672,000 for goodwill impairment, $1,430,000 for the write-off of PARSEC® System related assets and $1,413,000 of the recorded severance costs described above, and a loss from domestic operations of $1,999,000, which included charges of $1,180,000 for goodwill impairment, $244,000 for the write-off of PARSEC® System related assets and $585,000 of the recorded severance costs described above. Domestic operations include corporate expenditures, including costs relating to our status as a public company.

OTHER INCOME, NET

Interest income decreased $143,000 to $292,000 in 2008 from $435,000 in 2007 due principally to lower average cash balances and lower average yields, including the effect of maximum or default contractual interest rates paid to us in the earlier part of 2008 on the auction rate securities then held by us, which rates, under the terms of the auction rate securities' governing documents, expired and subsequently converted to below market rates. Interest income in 2008 also includes interest we received in conjunction with our receipt of a tax payment from the Italian government. Other income, net totaled $253,000 during 2008, compared to other income, net of $120,000 in 2007. Amounts included in other income, net in 2008 and 2007 were primarily net foreign currency gains or losses on transactions, particularly by our Italian subsidiary, which were denominated in currencies other than the subsidiary's functional currency. Also included in other income was a $661,000 decline in fair value of our investment in auction rate securities that was equally offset by a gain of $661,000 from a put option recorded as a result of rights we received from UBS, the international securities brokerage firm that held all the auction rate securities in which we invested, upon our election to sell to UBS all of the auction rate securities in which we invested at their par value of $4,100,000 at any time during the two-year period beginning January 2, 2009 (See Note 2, *Marketable Securities*, in the accompanying consolidated financial statements). We exercised these rights on January 2, 2009 and received all of the $4,100,000 par value of these auction rate securities on January 5, 2009.

INCOME TAX PROVISION (BENEFIT)

We recorded an income tax provision of $106,000 during 2008 and a tax benefit of $329,000 during 2007. The current portion of our tax provision in 2008 relates to Italian local income taxes based upon applicable statutory rates effective in Italy, while the deferred tax provision relates to domestic tax deductible goodwill. The tax benefit in 2007 relates to the domestic deferred tax benefit, recorded due to the adjustment of our deferred tax liability relating to tax deductible goodwill, recognized as a result of the goodwill impairment charge taken at ImmunoVision, partially offset by a current tax provision related to Italian local income taxes based upon applicable statutory rates effective in Italy. No current domestic tax provision was recorded in 2008 due to the expected utilization of prior period net operating losses to offset current domestic taxable income. No current domestic tax benefit was recorded in 2007 despite our domestic losses because we had a full valuation allowance against the domestic net deferred income tax assets.

NET INCOME (LOSS)

We earned net income of $196,000 in 2008 compared to a net loss of $10,434,000 in 2007. Our basic and diluted net income per common share was $0.01 in 2008 compared to a basic and diluted net loss per common share of $0.38 in 2007. The net income in 2008 and net loss in 2007 resulted primarily from the various factors discussed above. See Note 2, *Summary of Significant Accounting Policies*, in the Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for a description of the calculation of income (loss) per share.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2008, our working capital was $15,304,000 compared to $9,732,000 at December 31, 2007. Cash and cash equivalents totaled $4,421,000 at December 31, 2008 and $3,901,000 at December 31, 2007. Short-term marketable securities were $4,100,000 at December 31, 2008 and $1,925,000 at December 31, 2007. Long-term marketable securities were $0 at December 31, 2008, and $4,100,000 at December 31, 2007.

In the years ended December 31, 2008 and 2007, available cash was typically invested in money market accounts and auction rate securities. Auction rate securities are floating rate debt securities with long-term maturities (generally between 20 and 30 years), the interest rates of which are reset periodically (typically every 28 or 35 days) through a competitive bidding process often referred to as a "Dutch auction." Despite the underlying long-term maturity of these securities, such securities were typically priced and subsequently traded as short-term investments because of their interest rate reset feature. The Dutch auction process has historically provided a liquid market for auction rate securities, as this mechanism generally allows existing investors to rollover their holdings and continue to own their respective securities at then existing market interest rates or to liquidate their holdings by selling their securities at par value. In early 2008, however, primarily due to the liquidity issues experienced in global credit and capital markets, many auctions for auction rate securities failed and the sellers of such securities have been unable to liquidate their securities. A seller must then wait until the next successful auction to attempt to sell its auction rate securities, unless there is a secondary market for the particular securities. As a result of a failed auction, however, the auction rate securities may pay interest to the holder at a maximum or default rate defined by the securities' governing documents.

During January 2008, all $6,025,000 of our portfolio of marketable securities, which were classified as short-term or long-term as of December 31, 2007, were sold through the Dutch auction process, with $1,925,000 of the proceeds then invested in select money market instruments and $4,100,000 of the proceeds reinvested in auction rate securities. All of the auction rate securities in which we invested were secured by pools of student loans, in excess of 90% of which were guaranteed under the Federal Family Education Loan Program ("FFELP"). We do not own, and have not invested in, any auction rate securities secured by mortgages or collateralized debt obligations.

As described above, during 2008, the uncertainties in the global credit and capital markets prevented sellers of auction rate securities, including us, from liquidating their holdings in auction rate securities. Since mid-February 2008, each of the remaining auction rate securities that we held, the par value of which was approximately $4,100,000 in the aggregate, experienced, and has continued to experience, failed auctions. As a result of these failed auctions, we were unable to liquidate our investment in these auction rate securities. We included the $4,100,000 of auction rate securities in long-term marketable securities in which we were invested in the accompanying consolidated balance sheet as of December 31, 2007 because we could not predict when future auctions related to these securities would be successful or when we would be able to otherwise liquidate our investment in these auction rate securities.

During August 2008, UBS, the international securities brokerage firm that held the auction rate securities in which we had invested, entered into a settlement in principle with the New York Attorney General, the Massachusetts Securities Division, the SEC and other state regulatory agencies represented by North American Securities Administrators Association. Under the terms of the settlement in principle, UBS communicated to us that it would redeem at par all auction rate securities held by its corporate clients during time periods beginning as early as January 1, 2009 and as late as June 30, 2010. During October 2008, we received an offer letter from UBS pursuant to which UBS was offering Auction Rate Securities Rights (the "Rights"). The Rights gave us, upon our election at any time during the two-year period beginning January 2, 2009, the right to sell to UBS, and required UBS to purchase from us upon such exercise, all of the auction rate securities in which we invested at their par value of $4,100,000 (the "Put Option").

As a result our acceptance of the Rights, we recognized an other-than-temporary impairment of $661,000 on these auction rate securities, which was equally offset by income of $661,000 from the Rights, representing the

fair value of the Put Option. At December 31, 2008, we have classified both the auction rate securities and the Rights as short-term marketable securities. We exercised the Rights on January 2, 2009 and received all of the $4,100,000 par value of these auction rate securities on January 5, 2009.

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

Net cash flows of $648,000 were used in operating activities during 2008 compared to $1,889,000 that were provided by operating activities during 2007. Cash used in operating activities during 2008 was primarily the result of the payment of approximately $2,315,000 of severance costs accrued for estimated costs associated with management and other personnel changes that were accrued during 2007. Included in this amount is the effect of a separation agreement and general release negotiated with Giorgio D'Urso upon his resignation, effective January 10, 2008, as our President and Chief Executive Officer and as a member of our Board of Directors. Pursuant to the separation agreement, we paid Mr. D'Urso a one-time lump-sum payment of $495,000 and terminated Mr. D'Urso's employment agreement that provided for Mr. D'Urso to serve as our President and Chief Executive Officer until February 24, 2010 at a minimum annual base salary of $348,519. The remaining severance costs paid during 2008 included the payment of a portion of the estimated costs for the terminations in 2007 of selected employees of Delta Biologicals, our Italian subsidiary. At December 31, 2008, we have no further obligations relating to these matters. Excluding the payment of these accrued severance costs, cash of approximately $1,667,000 was provided by operating activities during 2008 due to cash provided by changes in operating assets and liabilities, cash provided from operations from net income for 2008 of $196,000 and non-cash items of $626,000. The non-cash items include depreciation and amortization, the product license impairment charge, a net recovery of doubtful accounts receivable, non-cash compensation and deferred income taxes. Cash provided by changes in operating assets and liabilities was primarily the result of $935,000 provided as a result of collections of accounts receivable and $866,000 provided principally from tax receivable collections in Italy, which had previously been included in other assets on our balance sheet. Partially offsetting these amounts were reductions in cash of $742,000 utilized as a result of increases in inventory and $2,728,000 used for payments of accounts payable and accrued expenses, including the previously discussed severance payments. Cash provided during 2007 was primarily the result of the combination of the net loss for the period of $10,434,000 offset by non-cash items and cash provided from changes in operating assets and liabilities. The non-cash items, which total $7,926,000, include principally the goodwill impairment charge and the write-off of PARSEC® System related assets, each as described in further detail above, as well as depreciation and amortization and deferred income taxes. Cash provided by changes in operating assets and liabilities of $4,397,000 was partially the result of $1,718,000 received as a result of reductions in accounts receivable, primarily due to the effect of accounts receivable collections of previously outstanding accounts receivable balances based upon negotiated agreements with governmental regions in Italy acting on behalf of hospitals located within the region. Cash of $1,986,000 provided by an increase in accounts payable and accrued expenses was principally the result of severance costs accrued for estimated costs associated with management and other personnel changes that occurred, or were being negotiated, during 2007, including related to the separation agreement and general release negotiated with Giorgio D'Urso, described above, and estimated costs for the terminations of selected employees of Delta Biologicals, our Italian subsidiary, during 2007.

Net cash of $1,333,000 was provided by investing activities during 2008 compared to $65,000 that was used by investing activities during 2007. The increase in cash provided by investing activities in 2008 compared to 2007 was primarily the result of our net sales of marketable securities totaling $1,925,000, partially offset by capital expenditures and acquisition of equipment on lease. Additionally, in October 2007, we paid the third milestone payment of $438,000 under our license agreement to obtain a perpetual, worldwide, royalty-free license of product technology from an Italian diagnostics company. The resulting accrued license payable in the accompanying balance sheet as of December 31, 2008 is $140,000. We are now working with the Italian

diagnostics company to achieve the remaining performance objective, which includes, among other things, the condition for us to receive authorization for "CE Marking" in the European Union. The application for "CE Marking" was filed in January 2008, and we expect to pay the remaining license payable in the first quarter of 2010 upon receipt of this approval. This further delay in our anticipated receipt of approval is, in large part, due to a backlog of activity and limited available resources at the applicable notifying body required to obtain "CE Marking."

There were no financing activities during 2008 or 2007. We did not repurchase any of our common stock during 2008 or 2007, whether as part of the common stock repurchase program approved by our Board of Directors in May 2002 of otherwise.

Our product research and development expenditures are expected to be approximately $1,800,000 during 2009. 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 $700,000 will be required in 2009 to improve and expand our facilities, equipment and information systems. This estimate does not include, however, expenditures relating to our previously reported plans to continue our search to relocate to a new location for our corporate headquarters and the operations of Diamedix. There can be no assurance that we will be successful in our plans to expand or relocate our operations.

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

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

Off-Balance Sheet Arrangements. As of December 31, 2008, we had no off-balance sheet arrangements that are reasonably likely to have a current or future material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

CRITICAL ACCOUNTING POLICIES

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with GAAP. 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, stock compensation, the computation of fair-value measurements, 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 will usually last for a period of three to five years. In exchange, we typically include a Mago® Plus instrument, which remains our property, and any required instrument service, which are paid for by the customer through these reagent kit purchases over the life of the commitment. We recognize revenue from the reagent kit sales when title passes, which is generally at the time of shipment. Should actual reagent kit or instrument failure rates significantly increase, our future operating results could be negatively impacted by increased warranty obligations and service delivery costs.

ALLOWANCE FOR DOUBTFUL ACCOUNTS

We maintain allowances for doubtful accounts, particularly in Italy for the operations of our Italian subsidiary, for estimated losses resulting from the inability of our customers to make required payments. In many instances our receivables in Italy, while currently due and payable, take in excess of a year to collect. Additionally, we may receive payments based upon negotiated agreements with governmental regions in Italy, acting on behalf of hospitals located in the region, in satisfaction of previously outstanding accounts receivable balances. Consequently, we may consider the potential receipt of those types of payments in determining our allowance for doubtful accounts. If contemplated payments are not received when expected or at all, if negotiated agreements are not complied with in a timely manner or at all, or if the financial condition of our customers were to deteriorate resulting in an impairment of their ability to make payments, then our operating results could be materially adversely affected during the period in which the determination to increase the allowance for doubtful accounts is or was made. Our allowances for doubtful accounts were $358,000 at December 31, 2008 and $1,053,000 at December 31, 2007. We recorded a net credit/recovery of accounts receivable of $633,000 during 2008 while $14,000 was provided for losses on accounts receivable in 2007.

INVENTORY

We regularly review inventory quantities on hand, which include components for current or future versions of products and instrumentation. If necessary, we record a provision for excess and obsolete inventory based primarily on our estimates of component obsolescence, product demand and production requirements, as well as based upon the status of a product within the regulatory approval process. We capitalize inventory costs associated with marketed products, and certain unapproved products prior to regulatory approval and product launch, based on management's judgment of probable future economic benefit which includes an assessment of probability of future commercial use and net realizable value. With respect to instrumentation products, we purchase instrument parts, and in some cases manufacture instrument components, in preparation for the commercial launch of the instrument in amounts sufficient to support forecasted initial market demand. We do

not capitalize such inventory unless the product or instrument is considered to have a high probability of receiving regulatory approval. We may make this determination prior to our submission to the FDA of a 510(k) application or other required regulatory submission. In determining probability, if we are aware of any specific risks or contingencies that are likely to adversely impact the expected regulatory approval process, then we would not capitalize the related inventory but would instead expense it as incurred. Additionally, our estimates of future instrumentation and diagnostic kit product demand, or our judgment of probable future economic benefit, may prove to be inaccurate, in which case any resulting adjustments to the value of inventory would be recognized at the time of such determination and could adversely affect our operating results.

Inventory reserves were $460,000 and $549,000 as of December 31, 2008 and 2007, respectively. In addition to the write-offs related to the PARSEC® System during 2007, $83,000 was utilized in 2008, while $89,000 was charged to cost and expenses in 2007. Included in our inventory balance at December 31, 2008 was approximately $150,000 in Mago® 4 instrumentation and instrument components in anticipation of our pending commercial product launch and $195,000 of raw material inventory, substantially all of which has shelf life exceeding five years, relating to our hepatitis product, which is currently pending regulatory approval based upon our January 2008 submission requesting "CE Marking" in the European Union. During 2007, as a result of our decision to focus on the development of the Mago® 4 and put any further development of the PARSEC® System on hold indefinitely, we recorded an inventory write-down of PARSEC® System inventory that was acquired in anticipation of the projected commercial launch. The inventory write-down, which totaled $1,207,000, was composed of write-downs of raw materials, work-in-progress and finished goods inventory of $618,000, $515,000 and $74,000, respectively.

GOODWILL AND OTHER INTANGIBLES

Pursuant to SFAS No. 142, *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, success of research and development projects, business trends, prospects and market conditions, to determine the fair value of the respected assets. If these or other estimates or their related assumptions change in the future, we may be required to record impairment charges for these assets not previously recorded. Any resulting impairment loss would be recorded as a charge against our earnings and could have a material adverse impact on our financial condition and results of operations.

We performed our annual test of our remaining goodwill at ImmunoVision as of December 31, 2008 by comparing the fair value of our ImmunoVision reporting unit with its carrying amount, including the goodwill. Fair value was determined primarily based upon the income approach, which estimates the fair value based on the future discounted cash flows, as well as the market approach, which estimates the fair value based on market prices of comparable companies. Based upon this methodology, no impairment was noted in 2008. Although we considered our current market capitalization, we did not believe it to be an appropriate measure for the fair value of ImmunoVision, as ImmunoVision represents less than 10% of our net revenues and total assets, and we believe that it is more meaningful to compute fair value based primarily upon discounted cash flows.

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

The determination as to whether a write-down of goodwill is necessary involves significant judgment based upon our short-term and long-term projections for the Company. The assumptions supporting the estimated future cash flows of the reporting unit, including profit margins, long-term forecasts, discount rates and terminal growth rates, reflect our best estimates. The continued decline in our market capitalization could potentially require us to record additional impairment charges in future periods for the remaining goodwill for ImmunoVision.

Our product license is existing technology, obtained from an Italian diagnostics company that had developed and successfully commercialized this technology to manufacture hepatitis products sold by them and for which it had already received "CE Marking" approval from the European Union. Through the acquisition of this existing technology in its current form, we expect to be able to derive revenue from the manufacture and sale of new hepatitis products. In exchange for the Italian diagnostics company's assistance in transferring the know-how of the manufacturing technology, we agreed to pay a total of 1,000,000 Euro in the form of four milestone payments upon the Italian diagnostics company's achievement of certain enumerated performance objectives related to the transfer of such existing technology.

During the fourth quarter of 2008, we determined that the carrying amount of the product license was in excess of its fair value and recorded a non-cash impairment charge to operations totaling $560,000, reducing the carrying value of the product license to $683,000 as of December 31, 2008, from $1,243,000 as of December 31, 2007. Fair value was determined based upon the income approach, which estimates fair value based upon future discounted cash flows. Following the results of the recently concluded inspection by the applicable notifying body required to obtain "CE Marking," we revised our assumptions supporting our computation of discounted cash flows to reflect the further delay in product launch and the possibility of a decrease in projected market share as a result of this delay, as well as to estimate the impact of the current global economic conditions. Based upon this methodology, and utilizing significant assumptions in the income approach that included a forecasted cash flow period of seven years and revenue and gross margin estimates, a range of potential outcomes was determined and weighted based upon an estimated probability of occurance. Estimated future cash flows generated by the technology granted by the product license was then calculated using a discount rate of 20%, reflecting our best estimate of fair value. While we determined that our payment of the final milestone payment is probable and believe that capitalization of the remaining recoverable asset is appropriate, there remains a risk that we will not be able to obtain product technology that would enable us to manufacture our own hepatitis products or, if we obtain such product technology, that we will not otherwise be able to manufacture our own hepatitis products. While we believe that we will be able to bring these hepatitis kits to market, if the progress of our efforts to begin marketing these kits is further adversely impacted, then we may be required to record an additional impairment charge with respect to all or a portion of the remaining $683,000 intangible product license of hepatitis technology asset.

STOCK-BASED COMPENSATION

Stock-based compensation expense for all stock-based compensation awards is based on the grant-date fair value estimate in accordance with the provisions of SFAS No. 123(R), *Share-Based Payment*. 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 United States Treasury yield curve in effect at the time of the grant.

INCOME TAXES

We have historically experienced net domestic losses from operations. GAAP requires 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, we have provided a full valuation allowance against our domestic deferred tax assets. Additionally, we have no net foreign deferred tax asset, as a full valuation allowance was established in March 2005 as a result of losses generated by our Italian operation. Over time we may reach levels of profitability that could cause our management to conclude that it is more likely than not that we will realize all or a portion of our net operating loss carryforwards and other temporary differences. Upon reaching such a conclusion, and upon such time as we reverse the entire valuation allowance against the deferred tax asset, we would then provide for income taxes at a rate equal to our effective tax rate.

Under Section 382 of the Internal Revenue Code, our use of our net operating loss carryforwards will be limited in the future as a result of the September 2, 2008 acquisition by the Debregeas-Kennedy Group of the approximately 72.3% of our outstanding shares of our common stock previously owned by Teva. The limitations of these net operating loss carryforwards did not impact our results for the year ended December 31, 2008. As a result of these limitations, utilization of our net operating loss carryforwards is limited to approximately $900,000 per year, plus any loss attributable to any built-in gain on assets sold within five years after the ownership change.

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 GAAP, 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 May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* ("SFAS No. 162"), which has been established by the FASB as a framework for entities to identify the sources of accounting principles and for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP. SFAS No. 162 is not expected to result in a change in current practices. SFAS No. 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board's ("PCAOB") amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. Accordingly, we adopted SFAS No. 162 in 2008.

In April 2008, the FASB issued FSP 142-3, *Determination of the Useful Life of Intangible Assets*, which amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Intangible Assets*. FSP 142-3 is effective for fiscal years beginning after December 15, 2008. We are currently evaluating the impact on our consolidated financial position of the guidance under FSP 142-3.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivatives and Hedging Activities* ("SFAS No. 161"), which enhances the requirements under SFAS No. 133, *Accounting for Derivatives and Hedging Activities*. SFAS No. 161 requires enhanced disclosures about an entity's derivatives and hedging activities and how they affect an entity's financial position, financial performance, and cash flows. This Statement will be effective for fiscal years and interim periods beginning after November 15, 2008. We do not expect the adoption of SFAS No. 161 to impact our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements* ("SFAS No. 160"). SFAS No. 160 amends Accounting Research Bulletin No. 51 to establish accounting and reporting standards for the noncontrolling (minority) interest in a subsidiary and for the

deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements and establishes a single method of accounting for changes in a parent's ownership interest in a subsidiary that do not result in deconsolidation. SFAS No. 160 is effective for fiscal years beginning on or after December 15, 2008. We do not expect the adoption of SFAS No. 160 to have a significant impact on our consolidated financial statements unless a future transaction results in a noncontrolling interest in a subsidiary.

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

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* ("SFAS No. 159"). SFAS No. 159 permits a company to choose to measure many financial instruments and other items at fair value that are not currently required to be measured at fair value. The objective is to improve financial reporting by providing a company with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007 and, accordingly, we adopted the provisions of this Statement on January 1, 2008. As a result of the adoption of SFAS No. 159 we elected to offset the subsequent price movements of our auction rate securities as discussed in Note 2, *Significant Accounting Policies,* under the heading Marketable Debt Securities, in our consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ("SFAS No. 157"), which defines fair value, establishes a framework for measuring fair value under GAAP, and expands disclosures about fair value measurements. This Statement does not require any new fair value measurements, but provides guidance on how to measure fair value by providing a fair value hierarchy used to classify the source of the information. For financial assets and liabilities, SFAS No. 157 is effective beginning January 1, 2008. In February 2008, the FASB deferred the effective date of SFAS No. 157 for all non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually) until January 1, 2009. We believe the impact will not require material modification related to our non-recurring fair value measurements and will be substantially limited to expanded disclosures in the notes to our consolidated financial statements for notes that currently have components measured at fair value. Effective January 1, 2008, we adopted SFAS No. 157 for financial assets and liabilities measured at fair value on a recurring basis. The partial adoption of SFAS No. 157 for financial assets and liabilities resulted in increased disclosure but did not have a material impact on our consolidated financial position, results of operations or cash flows.

CURRENCY FLUCTUATIONS

For the years ended December 31, 2008 and 2007, approximately 31.5% and 31.3%, 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 $478,000

in net revenues in 2008 compared to 2007. During the years ended December 31, 2008 and 2007, none of our subsidiaries were domiciled in a highly inflationary environment and the impact of inflation and changing prices on our net revenues and on our loss from continuing operations was not material.

During 2008, our subsidiary in Italy generated 31.5% of our net revenues. Conducting an international business inherently involves a number of difficulties, risks, and uncertainties, such as export and trade restrictions, inconsistent and changing regulatory requirements, tariffs and other trade barriers, cultural issues, labor and employment laws, longer payment cycles, problems in collecting accounts receivable, political instability, local economic downturns, seasonal reductions in business activity in Europe during the traditional summer vacation months, and potentially adverse tax consequences.

INCOME TAXES

We recognized an income tax provision of $106,000 for the year ended December 31, 2008 compared to an income tax benefit of $329,000 for the year ended December 31, 2007. Our income tax provision or benefit for the years ended December 31, 2008 and 2007 was different from the amount computed on the income (loss) before income taxes at the statutory rate of 35% primarily due to changes in the valuation allowance. No current domestic tax provision was recorded during 2008 or 2007 due to the expected utilization of prior period net operating losses to offset current domestic taxable income. The foreign current income tax provision during 2008 and 2007 was a result of Italian local income taxes based upon applicable statutory rates effective in Italy. Our 2007 deferred income tax was the result of domestic tax deductible goodwill, including the effect of a deferred tax benefit of $460,200 recorded as a result of the third quarter 2007 impairment charge against the goodwill at ImmunoVision.

As of December 31, 2008, we had no net domestic deferred tax asset, as a full valuation allowance has been established against our domestic deferred tax assets. We also had no net foreign deferred tax asset, as a result of the creation of a foreign valuation allowance in the first quarter of 2005 to fully reserve the remaining foreign deferred tax asset due to losses by our Italian operations. Additionally, as of December 31, 2008, we had net deferred tax liabilities relating to tax deductible goodwill of $238,000 at ImmunoVision, and we recorded a corresponding deferred tax provision of $63,000 during 2008. 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.

Under Section 382 of the Internal Revenue Code, our use of our net operating loss carryforwards will be limited in the future as a result of the September 2, 2008 acquisition by the Debregeas-Kennedy Group of the approximately 72.3% of our outstanding shares of our common stock previously owned by Teva. The limitations of these net operating loss carryforwards did not impact our results for the year ended December 31, 2008. As a result of these limitations, utilization of our net operating loss carryforwards is limited to approximately $900,000 per year, plus any loss attributable to any built-in gain on assets sold within five years after the ownership change.

RISK OF PRODUCT LIABILITY CLAIMS

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

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not required.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

IVAX Diagnostics, Inc. and Subsidiaries

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

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

In our opinion, the consolidated financial statements listed in the accompanying index present fairly, in all material respects, the financial position of IVAX Diagnostics, Inc. (the "Company") and its subsidiaries at December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the two years in the period ended December, 31, 2008 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP
Philadelphia, PA
March 30, 2009

IVAX Diagnostics, Inc. and Subsidiaries

Consolidated Balance Sheets
December 31, 2008 and 2007

	2008	2007
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 4,420,900	$ 3,900,564
Marketable securities	4,100,000	1,925,000
Accounts receivable, net of allowances for doubtful accounts of $358,268 and $1,052,797, respectively	5,789,901	6,287,654
Inventories, net	4,678,069	4,013,312
Other current assets	271,069	374,579
Total current assets	19,259,939	16,501,109
PROPERTY, PLANT AND EQUIPMENT:		
Land	352,957	352,957
Buildings and improvements	3,017,017	3,039,902
Machinery and equipment	2,716,258	2,534,084
Furniture and fixtures	1,898,191	1,887,369
	7,984,423	7,814,312
Less—Accumulated depreciation	(6,135,786)	(5,969,020)
	1,848,637	1,845,292
OTHER ASSETS:		
Marketable securities	—	4,100,000
Goodwill	870,290	870,290
Equipment on lease, net	210,743	163,113
Product license	682,936	1,242,936
Other	175,523	1,045,592
	1,939,492	7,421,931
Total assets	$ 23,048,068	$ 25,768,332
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 698,693	$ 1,217,408
Accrued license payable	140,062	147,184
Accrued expenses	3,116,755	5,404,372
Total current liabilities	3,955,510	6,768,964
OTHER LONG-TERM LIABILITIES:		
Deferred tax liabilities	238,200	174,708
Other long-term liabilities	902,551	850,177
Total other long-term liabilities	1,140,751	1,024,885
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Common stock, par value $0.01, authorized 50,000,000 shares, issued and outstanding 27,649,887 in 2008 and 2007	276,498	276,498
Additional paid-in capital	41,065,840	40,910,677
Accumulated deficit	(23,013,933)	(23,209,941)
Accumulated other comprehensive loss	(376,598)	(2,751)
Total shareholders' equity	17,951,807	17,974,483
Total liabilities and shareholders' equity	$ 23,048,068	$ 25,768,332

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, 2008 and 2007

	2008	2007
NET REVENUE	$20,819,175	$ 19,975,870
COST OF SALES	8,388,132	8,399,399
Gross profit	12,431,043	11,576,471
OPERATING EXPENSES:		
Selling	4,932,981	5,485,532
General and administrative	5,364,041	7,730,164
Research and development	1,817,047	2,152,114
Write-off of PARSEC® related assets	—	1,673,824
Impairment of product license and goodwill	560,000	5,852,435
Total operating expenses	12,674,069	22,894,069
Loss from operations	(243,026)	(11,317,598)
OTHER INCOME, NET:		
Interest income	292,231	435,575
Other income, net	253,217	119,515
Total other income, net	545,448	555,090
Income (loss) before income taxes	302,422	(10,762,508)
INCOME TAX PROVISION (BENEFIT)	106,414	(328,769)
Net income (loss)	$ 196,008	$(10,433,739)
Income (loss) per share		
Basic and diluted	$ 0.01	$ (0.38)
WEIGHTED AVERAGE SHARES OUTSTANDING:		
Basic	27,649,887	27,649,887
Diluted	27,649,887	27,649,887

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, 2008 and 2007

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
	Shares	Amount				
BALANCE, December 31, 2006	27,649,887	$276,498	$40,781,825	$(12,776,202)	$(543,979)	$ 27,738,142
Comprehensive loss:						
Net loss	—	—	—	(10,433,739)	—	(10,433,739)
Translation adjustment	—	—	—	—	541,228	541,228
Comprehensive loss						(9,892,511)
Stock compensation	—	—	128,852	—	—	128,852
BALANCE, December 31, 2007	27,649,887	$276,498	$40,910,677	$(23,209,941)	$ (2,751)	$ 17,974,483
Comprehensive loss:						
Net income	—	—	—	196,008	—	196,008
Translation adjustment	—	—	—	—	(373,847)	(373,847)
Comprehensive income						(177,839)
Stock compensation	—	—	155,163	—	—	155,163
BALANCE, December 31, 2008	27,649,887	$276,498	$41,065,840	$(23,013,933)	$(376,598)	$ 17,951,807

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, 2008 and 2007

	2008	2007
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$ 196,008	$(10,433,739)
Adjustments to reconcile net loss to net cash provided by operating activities—		
Depreciation and amortization	480,970	677,074
Net (recovery)/provision for doubtful accounts receivable	(633,238)	14,016
Non-cash compensation, including fair value adjustments of liability awards	155,163	105,852
Deferred income tax provision/(benefit)	63,492	(397,381)
Impairment of product license	560,000	—
Impairment of goodwill	—	5,852,435
Write-off of certain PARSEC instrumentation assets including prior period depreciation in 2006	—	1,673,824
Changes in operating assets and liabilities:		
Accounts receivable	935,162	1,718,003
Inventories	(742,143)	489,414
Other current assets	99,230	(26,187)
Other assets	865,965	1,544
Accounts payable and accrued expenses	(2,727,675)	1,986,473
Other long-term liabilities	98,818	227,686
Net cash provided by (used in) operating activities	(648,248)	1,889,014
CASH FLOWS FROM INVESTING ACTIVITIES:		
Capital expenditures	(407,288)	(175,926)
Acquisition of equipment on lease	(184,964)	(76,289)
Acquisition of product license	—	(438,000)
Purchases of marketable securities	—	(575,000)
Proceeds from sales of marketable securities	1,925,000	1,200,000
Net cash provided by (used in) investing activities	1,332,748	(65,215)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from stock option exercises	—	—
Net cash provided by financing activities	—	—
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(164,164)	81,035
NET INCREASE IN CASH AND CASH EQUIVALENTS	520,336	1,904,834
CASH AND CASH EQUIVALENTS, beginning of year	3,900,564	1,995,730
CASH AND CASH EQUIVALENTS, end of year	$ 4,420,900	$ 3,900,564
SUPPLEMENTAL DISCLOSURES:		
Income taxes paid	$ 136,944	$ 97,141

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

1 ORGANIZATION AND OPERATIONS

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

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

On September 2, 2008, a group comprised of Debregeas & Associes Pharma SAS, a company wholly-owned by Patrice R. Debregeas and members of his family, Paul F. Kennedy and Umbria LLC, a company wholly-owned by Mr. Kennedy, purchased from Teva all of the approximately 72.3% of the outstanding shares of our common stock owned by Teva, indirectly through its wholly-owned IVAX subsidiary, for an aggregate purchase price of $14,000,000, or $0.70 per share. For purposes of this Annual Report on Form 10-K, Debregeas & Associes Pharma SAS, Patrice R. Debregeas, Paul F. Kennedy and Umbria LLC are collectively known as the Debregeas-Kennedy Group.

2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

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

Use of Estimates

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

Recently Issued Accounting Standards

In May 2008, the FASB issued SFAS No. 162, *The Hierarchy of Generally Accepted Accounting Principles* ("SFAS No. 162"), which has been established by the FASB as a framework for entities to identify the sources of accounting principles and for selecting the principles to be used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP. SFAS No. 162 is not expected to result in

a change in current practices. SFAS No. 162 is effective 60 days following the SEC's approval of the Public Company Accounting Oversight Board's ("PCAOB") amendments to AU Section 411, *The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles*. Accordingly, the Company adopted SFAS No. 162 in 2008.

In April 2008, the FASB issued FSP 142-3, *Determination of the Useful Life of Intangible Assets*, which amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Intangible Assets*. FSP 142-3 is effective for fiscal years beginning after December 15, 2008. The Company is currently evaluating the impact on its consolidated financial position of the guidance under FSP 142-3.

In March 2008, the FASB issued SFAS No. 161, *Disclosures about Derivatives and Hedging Activities* ("SFAS No. 161"), which enhances the requirements under SFAS No. 133, *Accounting for Derivatives and Hedging Activities*. SFAS No. 161 requires enhanced disclosures about an entity's derivatives and hedging activities and how they affect an entity's financial position, financial performance, and cash flows. This Statement will be effective for fiscal years and interim periods beginning after November 15, 2008. The Company does not expect the adoption of SFAS No. 161 to impact its consolidated financial statements.

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

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

In February 2007, the FASB issued SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities Including an Amendment of FASB Statement No. 115* ("SFAS No. 159"). SFAS No. 159 permits a company to choose to measure many financial instruments and other items at fair value that are not currently required to be measured at fair value. The objective is to improve financial reporting by providing a company with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. SFAS No. 159 is effective for fiscal years beginning after November 15, 2007 and, accordingly, the Company adopted the provisions of this Statement on January 1, 2008. As a result of the adoption of SFAS No. 159 the Company elected to offset the subsequent price movements of its auction rate securities as discussed in Note 2, *Significant Accounting Policies,* under the heading Marketable Debt Securities, in its consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements* ("SFAS No. 157"), which defines fair value, establishes a framework for measuring fair value under GAAP, and expands disclosures about fair value measurements. This Statement does not require any new fair value measurements, but provides

guidance on how to measure fair value by providing a fair value hierarchy used to classify the source of the information. For financial assets and liabilities, SFAS No. 157 is effective beginning January 1, 2008. In February 2008, the FASB deferred the effective date of SFAS No. 157 for all non-financial assets and non-financial liabilities, except those that are recognized or disclosed at fair value in the financial statements on a recurring basis (at least annually) until January 1, 2009. The Company believes the impact will not require material modification related to our non-recurring fair value measurements and will be substantially limited to expanded disclosures in the notes to its consolidated financial statements for notes that currently have components measured at fair value. Effective January 1, 2008, the Company adopted SFAS No. 157 for financial assets and liabilities measured at fair value on a recurring basis. The partial adoption of SFAS No. 157 for financial assets and liabilities did not have a material impact on the Company's consolidated financial position, results of operations or cash flows.

Cash and Cash Equivalents

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

Marketable Debt Securities

Substantially all of the Company's cash and cash equivalents are presently held at one international securities brokerage firm, UBS. Accordingly, the Company is subject to credit risk if this brokerage firm is unable to repay the balance in the account or deliver the Company's securities or if the brokerage firm should become bankrupt or otherwise insolvent. It is the Company's policy to invest in select money market instruments, United States treasury investments, municipal and other government agency securities and corporate issuers. Realized gains and losses from sales of marketable securities are based on the specific identification method. At December 31, 2008 and December 31, 2007, the Company owned short-term marketable securities totaling $4,100,000 and $1,925,000, respectively. The short-term marketable securities owned at December 31, 2007 were sold during the year ended December 31, 2008 and are now invested in select money market instruments. Historically, the Company's short-term marketable securities were invested in auction rate securities with long-term maturities (generally between 20 and 30 years), the interest rates of which were reset periodically (typically every 28 or 35 days) through a competitive bidding process often referred to as a "Dutch auction." Despite the underlying long-term maturity of these securities, such securities were typically priced and subsequently traded as short-term investments because of their interest rate reset feature. During the year ended December 31, 2008, the Company received proceeds of $1,925,000 from the sale of marketable securities. During the year ended December 31, 2007, the Company used $575,000 for the purchase of marketable securities and received proceeds of $1,200,000 from the sale of marketable securities.

The Dutch auction process has historically provided a liquid market for auction rate securities, as this mechanism generally allows existing investors to rollover their holdings and continue to own their respective securities at then existing market interest rates or to liquidate their holdings by selling their securities at par value. In early 2008, however, primarily due to the liquidity issues experienced in global credit and capital markets, many auctions for auction rate securities failed and the sellers of such securities have been unable to liquidate their securities. A seller must then wait until the next successful auction to attempt to sell its auction rate securities, unless there is a secondary market for the particular securities. As a result of a failed auction, however, the auction rate securities may, for a specified period, pay interest to the holder at a maximum or default contractual rate defined by the securities' governing documents. Following the expiration of this period, the auction rate securities may pay interest at below market rates. At such time as the interest paid on the below market rates offsets for the interest paid at the previously paid maximum or default contractual rate, the auction rate securities will generally then pay interest at approximately market rate.

During January 2008, all $6,025,000 of the Company's portfolio of marketable securities, which were classified as short-term or long-term as of December 31, 2007, were sold through the Dutch auction process, with $1,925,000 of the proceeds then invested in select money market instruments and $4,100,000 of the proceeds

reinvested in auction rate securities. All of the auction rate securities in which the Company invested were secured by pools of student loans, in excess of 90% of which were guaranteed under the Federal Family Education Loan Program ("FFELP"), and each security had a credit rating of AAA or Aaa when purchased. The Company does not own, and has not invested in, any auction rate securities secured by mortgages or collateralized debt.

As described above, during 2008, uncertainties in the global credit and capital markets prevented sellers of auction rate securities, including the Company, from liquidating their holdings in auction rate securities. Since mid-February 2008, each of the remaining auction rate securities that the Company held, the par value of which is approximately $4,100,000 in the aggregate, experienced, and has continued to experience, failed auctions. As a result of these failed auctions, the Company was unable to liquidate its investment in these auction rate securities. The Company included the $4,100,000 of auction rate securities in which it was invested in long-term marketable securities in the accompanying consolidated balance sheet as of December 31, 2007 because it could not predict when future auctions related to these securities would be successful or when the Company would be able to otherwise liquidate its investment in these auction rate securities.

During August 2008, UBS, the international securities brokerage firm that held the auction rate securities in which the Company had invested, entered into a settlement in principle with the New York Attorney General, the Massachusetts Securities Division, the SEC and other state regulatory agencies represented by North American Securities Administrators Association. Under the terms of the settlement in principle, UBS had communicated to the Company that it would redeem at par all auction rate securities held by its corporate clients during time periods beginning as early as January 1, 2009 and as late as June 30, 2010. During October 2008, the Company received an offer letter from UBS pursuant to which UBS was offering Auction Rate Securities Rights (the "Rights"). The Rights gave the Company, upon its election at any time during the two-year period beginning January 2, 2009, the right to sell to UBS, and required UBS to purchase from the Company upon such exercise, all of the auction rate securities in which the Company invested at their par value of $4,100,000 (the "Put Option").

The Put Option represents a freestanding, non-transferable financial instrument that is initially measured and recorded at fair value and accounted for separately from the auction rate securities. Because the Put Option does not meet the definition of a derivative under SFAS No. 133, it is not subsequently adjusted for changes in its fair value. In substance, however, the Put Option acts as a hedge to protect against the future decline in fair value of the auction rate securities, and the estimated value of the Put Option represents the incremental value associated with the ability to recover the full cost of the auction rate securities. To better account for the substance of the arrangement, the Company believes that the future changes in the fair value of the Put Option should be recognized in order to offset subsequent price movements of the auction rate securities. Therefore, the Company elected the fair value option set forth in SFAS No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities—Including an amendment of FASB Statement No. 115* (SFAS No. 159), to account for the Put Option. Under SFAS No. 159, all subsequent changes in fair value of the Put Option will be recognized in earnings. The Company therefore recognized $660,563, representing the fair value of the Put Option at December 31, 2008, within marketable securities on its consolidated balance sheet as of December 31, 2008, and a corresponding gain during the year ended December 31, 2008 associated with the fair value of the Put Option within other income on its consolidated statement of operations for the year ended December 31, 2008. The fair value of the Put Option has been estimated using significant unobservable inputs because there is not an observable market for the Put Option. Accordingly, the fair value of the Put Option has been included as a Level 3 asset within the SFAS No. 157 hierarchy (See Note 7, *Fair Value Measurement*).

During October 2008, the Company accepted UBS' offering of the Rights. Prior to October 2008, the Company characterized and accounted for the declines in the fair value of the auction rate securities in which it invested as temporary, as the Company continued to expect to hold these securities until such time as it was able to receive at least par value for its investments and, given the current uncertainty in the credit markets, the Company expected this would be longer than 12 months. Accordingly, related unrealized losses had been

recorded as a component of equity within other comprehensive income. By accepting the Rights, however, the Company can no longer demonstrate the positive intent to hold these securities indefinitely. As such, during the fourth quarter of 2008, the Company recognized within other income on its consolidated statement of operations for the year ended December 31, 2008 an other-than-temporary impairment charge of $660,563 associated with all previously accumulated unrealized losses relating to the auction rate securities in which it invested. This charge was equal in amount to the corresponding gain recognized from the Put Option discussed above, resulting in no net charge to other income in the year ended December 31, 2008. The Company exercised the Rights on January 2, 2009 and received all of the $4,100,000 par value of these auction rate securities on January 5, 2009.

Accounts Receivable and Allowance for Doubtful Accounts

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

The Company periodically receives payments based upon negotiated agreements with governmental regions in Italy, acting on behalf of hospitals located in the region, in satisfaction of previously outstanding accounts receivable balances. The Company may have anticipated collection of these amounts through a payment as described above and, therefore, not provided an allowance for doubtful accounts for these amounts. Future payments by governmental regions in Italy are possible and, as a result, the Company may consider the potential receipt of those payments in determining its allowance for doubtful accounts. If contemplated payments are not received when expected or at all, or if negotiated agreements are not complied with in a timely manner or cancelled, then the Company may provide additional allowances for doubtful accounts.

The allowance for doubtful accounts was $358,268 and $1,052,797 at December 31, 2008 and 2007, respectively, and activity for the years then ended was as follows:

	2008	2007
Balance at January 1	$1,052,797	$1,093,070
(Recovery)/provision	(633,238)	14,016
Write-offs	(54,582)	(132,928)
Effects of changes in foreign exchange rates	(6,709)	78,639
Balance at December 31	$ 358,268	$1,052,797

Inventories

Inventories are stated at the lower of cost (first-in, first-out) or market. Components of inventory cost include materials, labor and manufacturing overhead. In evaluating whether inventory is stated at the lower of cost or market, management considers such factors as the amount of inventory on hand, estimated time required to sell such inventory, remaining shelf life and current market conditions. Inventory costs associated with marketed products are capitalized, as are certain unapproved products prior to regulatory approval and product launch, based on management's judgment of probable future economic benefit which includes an assessment of probability of future commercial use and net realizable value. With respect to instrumentation products, the Company purchases instrument parts and, in some cases, manufactures instrument components in preparation for the commercial launch of the instrument in amounts sufficient to support forecasted initial market demand. Inventory is not capitalized unless the product or instrument is considered to have a high probability of receiving regulatory approval. The Company may make this determination prior to its submission to the FDA of a 510(k)

application or other required regulatory submission. In determining probability, if the Company is aware of any specific risks or contingencies that are likely to adversely impact the expected regulatory approval process, then it would not capitalize the related inventory but would instead expense it as incurred. Reserves are provided as appropriate to reduce excess or obsolete inventories to the lower of cost or market. Inventories, net consist of the following:

	December 31,	
	2008	2007
Raw materials	$ 783,186	$ 718,909
Work-in-process	1,019,564	862,857
Finished goods	2,875,319	2,431,546
Total inventories, net	$4,678,069	$4,013,312

In accordance with our inventory accounting policy, total inventories at December 31, 2008 include components for current or future versions of products and instrumentation, including approximately $150,000 in Mago® 4 instrumentation and instrument components in anticipation of the future commercial product launch and $195,000 of raw material inventory, substantially all of which has a shelf life exceeding five years relating to the Company's hepatitis product, which is currently pending regulatory approval based upon the Company's January 2008 submission requesting "CE Marking" in the European Union. At December 31, 2007 Mago® 4 instrumentation and instrument components totaled $70,000 and hepatitis related inventory totaled $200,000. As discussed below in Note 3, *Write-off of PARSEC® Assets,* the Company's decision during the fourth quarter of 2007 that it intends to focus on the development of the Mago® 4 and put any further development of the PARSEC® System on hold indefinitely resulted in an inventory write-down during 2007 of PARSEC® System inventory that was acquired in anticipation of the projected commercial launch. The inventory write-down, which totaled $1,206,655, was composed of raw materials, work-in-progress and finished goods inventory of $617,994, $514,692 and $73,969, respectively.

Property, Plant and Equipment

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

	Years
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 $351,136 and $389,594 during the years ended December 31, 2008 and 2007, 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:

	December 31,	
	2008	2007
Equipment on lease, at cost	$6,328,661	$6,358,894
Less—Accumulated amortization	6,117,918	6,195,781
	$ 210,743	$ 163,113

Equipment on lease is typically amortized over three years. Amortization expense related to equipment on lease was $129,834 and $274,480 for the years ended December 31, 2008 and 2007, respectively.

Long Lived Assets Including Goodwill

Goodwill consists of the following:

	December 31,	
	2008	2007
Goodwill	$1,262,033	$1,262,033
Less—Accumulated amortization	391,743	391,743
	$ 870,290	$ 870,290

As discussed in Note 4, *Impairment of Long Lived Assets including Goodwill*, in accordance with SFAS 142, *Goodwill and Other Intangible Assets,* the Company tests goodwill for possible impairment on an annual basis and at any other time events occur or circumstances indicate that the carrying amount of goodwill may be impaired. During the third quarter of 2007, based principally upon the decline in the Company's market capitalization to less than its June 30, 2007 book value for the preceding seven weeks prior to the end of the third quarter of 2007, as well as the decision the Company made to change its strategic direction to place any further development of the PARSEC® System on hold indefinitely, the Company determined that there was sufficient indication to require it to assess whether any portion of its recorded goodwill balance was impaired. This assessment resulted in the Company recording a non-cash goodwill impairment charge to operations totaling $5,852,435 during 2007.

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

Product License

Through the acquisition of existing hepatitis technology under a perpetual, worldwide, royalty-free license, the Company expects to be able to derive revenue from the manufacture and sale of new hepatitis products following the completion of all of the performance objectives contained in the license agreement, which are required in order to complete the transfer of the technology to the Company. As discussed in Note 5, *Product*

License, Including Impairment Charge, the Company tests its product license for possible impairment. During the fourth quarter of 2008, the Company determined that the carrying amount of the product license was in excess of its fair value and, as a result, recorded a non-cash impairment charge to operations totaling $560,000, reducing the value of the product license to $682,936 as of December 31, 2008, from $1,242,936 as of December 31, 2007. Fair value was determined based upon the income approach, which utilized significant assumptions to estimate fair value based upon future discounted cash flows.

While the license is perpetual, the Company believes that the expected economic useful life of the license will be 4 to 6 years after the licensed technology has been transferred to the Company and the Company can utilize the licensed technology for its intended purpose. Amortization of the product license will then begin following the initial sale of the hepatitis products manufactured by the Company.

Foreign Currencies

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

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

Financial Instruments

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

Revenue Recognition

Revenue and the related cost of sales on sales of test kits and instruments are recognized when risk of loss and title passes, which is generally at the time of shipment. Net revenue is comprised of gross revenue less provisions for expected product returns, allowances and discounts and warranty claims. Provisions and discounts for the years ended December 31, 2008 and 2007 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.

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

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). Compensation

costs are recognized on a straight line basis over the requisite service period of the award, which is generally the option vesting term or immediately for options vested at the date of grant. 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 for the years ended December 31, 2008 and 2007.

At December 31, 2008, the Company had two stock-based employee compensation plans as described in Note 12, *Shareholders' Equity*. The Company recorded total compensation expense related to unvested options of $155,163 and $105,852 for the years ended December 31, 2008 and December 31, 2007, respectively.

Comprehensive Loss

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

	Year Ended December 31,	
	2008	2007
Net income (loss)	$ 196,008	$(10,433,739)
Foreign currency translation adjustment	(373,847)	541,228
Comprehensive loss	$(177,839)	$ (9,892,511)

Income (Loss) per Share

Income (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 are considered potential common stock. The dilutive effect, if any, of stock options is calculated using the treasury stock method.

A reconciliation of the denominator of the basic and diluted loss per share computation for the years ended December 31, 2008 and 2007 is as follows:

	Year Ended December 31,	
	2008	2007
Basic weighted average shares outstanding	27,649,887	27,649,887
Effect of diluted securities—Stock options	—	—
Diluted weighted average shares outstanding	27,649,887	27,649,887
Not included in the calculation of diluted loss per share because their impact is antidilutive:		
Stock options outstanding	1,127,249	784,949

3 WRITE-OFF OF PARSEC® ASSETS

The Company recorded a $1,673,824 write-off of net assets relating to the PARSEC® System during the fourth quarter of 2007. This write-off resulted from the Company's evaluation of the status of the development of its PARSEC® System and the decision it made during the fourth quarter of 2007 to change its strategic direction to focus on the development of its new Mago® 4 instrument as a platform for marketing the Company's kits and to place any further development of the PARSEC® System on hold indefinitely. As discussed in Note 2, *Summary of Significant Accounting Policies*, under the heading of *Inventories*, raw material, work-in-process and finished goods inventories comprised $1,206,655 of this write-off. Additionally, the remaining portion of this

write-off was composed of property, plant and equipment with a net book value of $337,912, equipment on lease with a net book value of $48,579 and other current assets of $80,678. These charges were included in operating expenses in the accompanying statements of operations for the year ended December 31, 2007.

4 IMPAIRMENT OF LONG-LIVED ASSETS INCLUDING GOODWILL

SFAS No. 142 *Goodwill and Other Intangible Assets* ("SFAS No. 142"), makes use of the concept of reporting units. All acquisitions must be assigned to a reporting unit or units. Reporting units have been defined under the standards to be the same as or one level below an operating segment, as defined in SFAS No. 131, *Disclosures About Segments of an Enterprise and Related Information* ("SFAS No. 131"). The Company had total goodwill of $870,219 as of December 31, 2008 and 2007, following the goodwill impairment loss recorded during the year ended December 31, 2007 with respect to both ImmunoVision and Delta Biologicals as discussed below. As of December 31, 2006, the Company had total goodwill of $6,722,725, of which $4,672,435 was assigned to Delta Biologicals, the Company's Italian reporting unit, and $2,050,290 was assigned to ImmunoVision, a component of the Company's domestic segment.

The Company tests goodwill for possible impairment on an annual basis and at any other time events occur or circumstances indicate that the carrying amount of goodwill may be impaired. The first step of the SFAS No. 142 impairment analysis consists of a comparison of the fair value of the reporting unit with its carrying amount, including the goodwill. For the December 31, 2008 annual test of its remaining goodwill at ImmunoVision, the Company determined fair value primarily based upon the income approach, which estimates the fair value based on the future discounted cash flows, as well as the market approach, which estimates the fair value based on market prices of comparable companies. The Company believes the income approach is more appropriate to determine the fair value at ImmunoVision and should therefore be more heavily weighted due to the facts that similar public companies comparable to ImmunoVision are difficult to identify and current market conditions are in a period of volatility with wide ranging multiples. Based upon this methodology, and utilizing significant assumptions in the income approach that included a forecasted cash flow period of five years, long-term annual growth rates of approximately 4% and a discount rate of 16%, no impairment was noted in 2008. Although the Company's current market capitalization was considered, the Company did not believe it to be an appropriate measure for the fair value of ImmunoVision, as ImmunoVision represents less than 10% of the net revenues and total assets of the Company. The Company believes that it is more meaningful to compute fair value based primarily upon discounted cash flows.

During the third quarter of 2007, based principally upon a decline in the Company's market capitalization to less than its June 30, 2007 book value for the preceding seven weeks prior to the end of the third quarter of 2007, as well as the decision the Company made to change its strategic direction and place any further development of the PARSEC® System on hold indefinitely, the Company determined that there was sufficient indication to require it to assess, in accordance with SFAS No. 142, whether any portion of its recorded goodwill balance was impaired. Calculations performed using the income approach, with respect to Delta Biologicals, assumed a forecasted cash flow period of five years, long-term annual growth rates of 5% and a discount rate of 17%, and with respect to ImmunoVision, a forecasted cash flow period of five years, long-term annual growth rates of 5% and a discount rate of 16%. The Company also considered its total market capitalization as of September 30, 2007, using an average closing price for the 15 days prior to and the 15 days following September 30, 2007.

Based on the first step analysis that was separately performed for each of Delta Biologicals and ImmunoVision, the Company determined that the carrying amount of the goodwill at each of Delta Biologicals and ImmunoVision in 2007 was in excess of its respective fair value. As a result, the Company was required to perform the second step analysis for each of Delta Biologicals and ImmunoVision in order to determine the amount of the goodwill impairment loss. The second step analysis consisted of comparing the implied fair value of the goodwill with the carrying amount of the goodwill, with an impairment charge resulting from any excess of the carrying value of the goodwill over the implied fair value of the goodwill based on a hypothetical allocation of the estimated fair value of each of Delta Biologicals and ImmunoVision. Based on the second step

analysis, the Company concluded that all $4,672,435 of the goodwill recorded at Delta Biologicals and $1,180,000 of the $2,050,290 of goodwill recorded at ImmunoVision was impaired. As a result, the Company recorded a non-cash goodwill impairment charge to operations totaling $5,852,435 during 2007.

The determination as to whether a write-down of goodwill is necessary involves significant judgment based on short-term and long-term projections of the Company. The assumptions supporting the estimated future cash flows of the reporting unit, including profit margins, long-term forecasts, discount rates and terminal growth rates, reflect the Company's best estimates. Additionally, while the Company assesses goodwill on an individual reporting unit basis, the continued decline in the Company's market capitalization could potentially require additional impairment charges to be recorded in future periods for the remaining goodwill for ImmunoVision.

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

5 PRODUCT LICENSE, INCLUDING IMPAIRMENT CHARGE

In September 2004, the Company entered into a license agreement with an Italian diagnostics company to obtain a perpetual, worldwide, royalty-free license of product technology used by the Italian diagnostics company. This licensed hepatitis product technology is existing technology, which the Italian diagnostics company had developed and successfully commercialized to manufacture hepatitis products sold by them and for which it had already received "CE Marking" approval from the European Union. Through the acquisition of this existing technology in its current form, the Company expects to be able to derive revenue from the manufacture and sale of new hepatitis products. In exchange for the Italian diagnostics company's assistance in transferring the know-how of the manufacturing technology, the Company agreed to pay a total of 1,000,000 Euro in the form of four milestone payments upon the Italian diagnostics company's achievement of certain enumerated performance objectives related to the transfer of such existing technology. Three of the four milestone payments, totaling 900,000 Euro, were made in prior years. The remaining milestone payment of $140,000 is included in accrued license payable in the accompanying consolidated balance sheet as of December 31, 2008. The Company is now working with the Italian diagnostics company to achieve the remaining performance objective, which includes, among other things, the condition for the Company to receive authorization for "CE Marking" in the European Union. The application for "CE Marking" was filed in January 2008 and, based upon the results of an inspection concluded by the applicable notifying body in January 2009, the Company now expects to pay the remaining license payable in the first quarter of 2010 upon receipt of authorization for "CE Marking," in large part, as a result of a backlog of activity and limited available resources at the applicable notifying body.

During the fourth quarter of 2008, the Company determined that the carrying amount of the product license was in excess of its fair value and recorded a non-cash impairment charge to operations totaling $560,000, reducing the value of the product license to $682,936 as of December 31, 2008, from $1,242,936 as of December 31, 2007. Fair value was determined based upon the income approach, which estimates fair value based upon future discounted cash flows. Following the results of the recently concluded inspection by the applicable notifying body required to obtain "CE Marking," the Company revised its assumptions supporting its computation of discounted cash flows to reflect the further delay in product launch and the possibility of a decrease in projected market share as a result of this delay, as well as to estimate the impact of the current global economic conditions. Based upon this methodology, and utilizing significant assumptions in the income approach that included a forecasted cash flow period of seven years and revenue and gross margin estimates, a range of potential outcomes was determined and weighted based upon an estimated probability of occurance. Estimated future cash flows generated by the technology granted by the product license was then calculated using a discount rate of 21%, reflecting the Company's best estimate of fair value.

While the license is perpetual, the Company believes that the expected economic useful life of the license will be 4 to 6 years after the licensed technology has been transferred to the Company and the Company can utilize the licensed technology for its intended purpose, which will occur after the completion of all of the performance objectives and payment of the fourth milestone payment. Amortization of the product license will begin following the successful technology transfer to the Company and the initial sale of the hepatitis products manufactured by the Company.

6 SEVERANCE COSTS

General and administrative expenses for the year ended December 31, 2007 include severance costs of $1,998,400, which were accrued as a result of anticipated costs associated with management and other personnel changes that occurred in, or were being negotiated during, the fourth quarter of 2007. Included in this amount is the effect of a separation agreement and general release negotiated with Giorgio D'Urso in connection with his resignation, effective January 10, 2008, as President and Chief Executive Officer of the Company and as a member of the Board of Directors of the Company. Pursuant to this separation agreement, the Company paid Mr. D'Urso a one-time lump-sum payment of $495,000, and the Company and Mr. D'Urso terminated his then existing employment agreement that provided for Mr. D'Urso to serve as President and Chief Executive Officer of the Company until February 24, 2010 and to receive a minimum annual base salary of $348,519. Additionally, the remaining severance costs include estimated costs in connection with the terminations of selected employees of Delta Biologicals, the Company's Italian subsidiary, in 2007. All payments were made in 2008, and no severance accruals were outstanding as of December 31, 2008.

7 FAIR VALUE MEASUREMENT

Effective January 1, 2008, the Company adopted SFAS No. 157, *Fair Value Measurements* ("SFAS No. 157"), which defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants at the measurement date. SFAS No. 157 establishes a three-level fair value hierarchy for disclosure to show the extent and level of judgment used to estimate fair value measurements. This hierarchy requires entities to maximize the use of observable inputs and minimize the use of unobservable inputs. The three levels of inputs used to measure fair value are as follows:

Level 1—Quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs other than quoted prices included in Level 1, such as quoted prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. This includes certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs.

In accordance with SFAS No. 157, the following table, which does not include cash on hand, represents the Company's fair value hierarchy for its financial assets (cash equivalents and available for sale investments) as of December 31, 2008:

	Fair Value	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$1,534,149	$1,534,149	$—	$ —
Marketable securities:				
Auction rate securities	3,439,437	—	—	3,439,437
Put Option (See Note 2)	660,563	—	—	660,563
Total financial assets	$5,634,149	$1,534,149	$—	$4,100,000

The auction rate securities in which the Company invested and the Put Option, both of which are discussed above in Note 2, *Summary of Significant Accounting Policies,* under the heading *Marketable Securities,* make up the combined balance of marketable securities of $4,100,000 at December 31, 2008 and the single asset valued under the Level 3 hierarchy. At December 31, 2008, the Company utilized a discounted cash flow approach to arrive at the valuation of $3,439,437. The assumptions used in preparing the discounted cash flow model include estimates for interest rates, timing and amount of cash flows, credit and liquidity premiums, underlying collateral and expected holding periods of the auction rate securities. These assumptions are volatile and subject to change as the underlying sources of these assumptions and market conditions change. They represent the Company's estimates given available data as of December 31, 2008.

As discussed in Note 2, *Summary of Significant Accounting Policies,* under the heading *Marketable Securities*, the Put Option acts as a hedge to protect against the decline in fair value of the auction rate securities, and the estimated value of the Put Option represents the incremental value associated with the ability to recover the full cost of the auction rate securities. The decline in fair value of the auction rate securities in which the Company invested was therefore offset by the value of the Put Option, resulting in a marketable security value of $4,100,000 as of December 31, 2008. As further discussed in Note 2, *Summary of Significant Accounting Policies,* on January 2, 2009, the Company exercised the Rights it received from UBS and, on January 5, 2009, received all of the $4,100,000 par value of these auction rate securities.

The following tables provide a summary of changes in fair value of the Company's investments in auction rate securities (Level 3) for the year ended December 31, 2008:

	Auction-rate Securities	Auction-rate Securities Put Option	Total
Balance January 1, 2008 (short-term and long-term)	$ 6,025,000	$ —	$ 6,025,000
Sale of auction rate securities	(1,925,000)	—	(1,925,000)
Total gains/(losses) realized in earnings in other income	(660,563)	660,563	—
Total gains/(losses) included in other comprehensive income	—	—	—
Balance December 31, 2008	$ 3,439,437	$660,563	$ 4,100,000

8 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, 2008 and 2007, $3,890,358 and $4,443,916, respectively, of total net accounts receivable were due in Italy. At December 31, 2008 and 2007, 50.9% and 58.3%, respectively, of total net accounts receivable were due from hospitals and laboratories controlled by the Italian government. The Company maintains allowances for doubtful accounts, particularly in Italy where payment cycles are longer than in the United States, for potential credit losses based on the age of the accounts receivable and the results of the Company's periodic credit evaluations of its customers' financial condition. Additionally, the Company periodically receives payments based upon negotiated agreements with governmental regions in Italy, acting on behalf of hospitals located in the region, in satisfaction of previously outstanding accounts receivable balances (see Note 2, *Summary of Significant Accounting Policies*, under the heading of *Accounts Receivable and Allowance for Doubtful Accounts*).

As referenced in Note 2, *Summary of Significant Accounting Policies* under the heading *Marketable Debt Securities*, substantially all cash and cash equivalents and marketable securities are presently held at one international securities brokerage firm, UBS. Accordingly, the Company is subject to credit risk if this brokerage firm is unable to repay the balance in the account or deliver the Company's securities or if the brokerage firm should become bankrupt or otherwise insolvent.

9 INCOME TAXES

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

The Company has established a full valuation allowance on its net domestic deferred tax assets, which are primarily comprised of net operating loss carryforwards. As of December 31, 2008 and 2007, the Company had no net domestic deferred tax asset, as domestic net operating losses generated prior to the merger between b2bstores.com and the pre-merger IVAX Diagnostics were utilized by IVAX and a full valuation allowance has been established against domestic deferred tax assets generated subsequent to March 14, 2001. As of December 31, 2008 and 2007, the Company had net deferred tax liabilities of $238,200 and $174,708, respectively, relating to tax deductible goodwill. During 2007, as a result of the impairment charge relating to a portion of the goodwill recorded at ImmunoVision (See Note 4—*Impairment of Long-Lived Assets Including Goodwill*), the Company reduced its deferred tax liability relating to tax deductible goodwill at ImmunoVision and recorded a corresponding deferred tax benefit of $460,200. Additionally, as of December 31, 2008 and 2007, the Company also had no net foreign deferred tax asset, as a full valuation allowance was provided during the first quarter of 2005 as a result of losses by the Company's Italian operation, and additional allowances have been provided for losses occurring since that date through December 31, 2008. 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:

	Year Ended December 31,	
	2008	2007
Current:		
Domestic	$ —	$ —
Foreign	42,922	68,612
Deferred:		
Domestic	63,492	(397,381)
Foreign	—	—
Total	$106,414	$(328,769)

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

	Year Ended December 31,	
	2008	2007
Domestic	$246,146	$ (1,447,645)
Foreign	56,276	(9,314,863)
Total	$302,422	$(10,762,508)

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

	December 31, 2008	December 31, 2007
Current:		
Accounts receivable allowances	$ 149,352	$ 301,024
Reserves and accruals	411,130	1,234,539
Capitalized inventory costs	146,827	126,901
Valuation allowance	(707,309)	(1,662,464)
Deferred income taxes	—	—
Long-Term:		
Depreciation and basis differences on fixed and intangible assets	573,912	48,205
Stock based compensation	185,833	126,094
Other	(21,980)	(17,641)
Foreign net operating losses	1,609,242	4,006,332
Domestic net operating losses	3,536,083	3,770,473
Valuation allowance	(5,883,090)	(7,933,463)
Net deferred tax asset	$ —	$ —

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

	December 31, 2008	December 31, 2007
Long-Term:		
Tax deductible goodwill	238,200	174,708
Net deferred tax liability	$238,200	$174,708

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, 2008	Year Ended December 31, 2007
Provision (benefit) for income taxes at U.S. Federal statutory rate of 35%	$105,848	$(3,766,878)
Change in valuation allowance (excluding portion relating to stock options)	(66,428)	3,355,666
Foreign tax rate differential and global permanent differences	66,914	82,443
Provision (benefit) for income taxes	$106,414	$ (328,769)

The Company's income tax provision or benefit for the years ended December 31, 2008 and 2007 was different from the amount computed on the income (loss) before provision (benefit) for income taxes at the statutory rate of 35% primarily due to changes in the valuation allowance, foreign tax rate differential and global permanent differences, as well as the deferred tax provision (benefit) recorded as a result of the goodwill impairment charge relating to ImmunoVision.

As discussed above, the Company has established a full valuation allowance on its net domestic deferred tax assets, which are primarily comprised of net operating loss carryforwards and, in 2005, provided a full valuation allowance on the foreign net deferred income tax assets. Net domestic operating losses generated by the

Company after March 14, 2001 total $9,067,000, of which $3,367,000 are available for use prior to their expiration in 2021, subject to any applicable limitations as described below. Additionally, net operating losses of $1,595,000, $350,000, $710,000, $2,514,000, $459,000 and $30,000 are available for use prior to their expirations in 2022, 2023, 2024, 2025, 2026 and 2027, respectively, subject to any applicable limitations as described below. Approximately $3,710,000 of the domestic net operating loss at December 31, 2008, representing approximately $1,447,000 ($0 for the years ended December 31, 2008 and 2007, 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.

Under Section 382 of the Internal Revenue Code, the Company's use of its net operating loss carryforwards will be limited in the future as a result of the September 2, 2008 acquisition by the Debregeas-Kennedy Group of the approximately 72.3% of the outstanding shares of the Company's common stock previously owned by Teva. The limitations of these net operating loss carryforwards did not impact the Company's results for the year ended December 31, 2008. As a result of these limitations, utilization of the Company's net operating loss carryforwards is limited to approximately $900,000 per year. The amount of the annual limitation will be adjusted upwards for any built-in gains on certain assets sold during the five year period commencing with the ownership change.

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.

As of December 31, 2008, the 2005-2007 tax years remain subject to examination by major tax jurisdictions. At each of December 31, 2007 and 2008, the Company had no unrecognized tax benefits. If uncertain tax positions had been recorded, then the Company would recognize interest and penalties related to uncertain tax positions in income tax expense.

10 EMPLOYEE BENEFIT PLAN

Beginning after the date of the merger between b2bstores.com and the pre-merger IVAX Diagnostics, the Company established its own 401(k) employee savings plan which allows for pre-tax employee payroll contributions and discretionary employer matching contributions. Matching contributions of $71,600 and $72,000 were made into this plan during the years ended December 31, 2008 and 2007, respectively.

11 ACCRUED EXPENSES

Accrued expenses consist of the following:

	December 31,	
	2008	2007
Payroll costs	$1,191,749	$ 775,346
Severance and related costs (Note 6)	—	2,459,372
Taxes, other than income taxes	1,106,603	1,287,853
Professional fees	293,563	249,853
Royalties	86,548	96,415
Other	438,292	535,533
	$3,116,755	$5,404,372

12 SHAREHOLDERS' EQUITY

Common Stock

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

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

Share Repurchase Program

During May 2002, the Company's Board of Directors approved a program to repurchase up to 1,000,000 shares of the Company's publicly held common stock. In December 2002, the Company's Board of Directors authorized an additional repurchase of up to 1,000,000 shares of the Company's publicly held common stock. During 2008 and 2007, the Company did not repurchase any shares of its common stock. The total number of shares of common stock repurchased by the Company since the inception of its repurchase program is 1,184,573.

Stock Option Plans

The Company maintains two stock option plans. The first, the IVAX Diagnostics, Inc. 1999 Stock Option Plan (the "1999 Plan"), became effective June 29, 1999 when approved by the Board of Directors and the sole stockholder of the pre-merger IVAX Diagnostics. The 1999 Plan permits the issuance of options to employees, non-employee directors and consultants to purchase up to 2,000,200 shares of the Company's common stock. As of December 31, 2006, no options to purchase shares of the Company's common stock were 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.

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 or greater than the closing market value of the stock on the date of the grant and with vesting, primarily for Company employees, ranging from all at once after six months to equal annual amounts over a four year period, and, for non-employee directors, immediately.

The following charts summarize option activity as of December 31, 2008 and changes during the years ended December 31, 2008 and 2007 under the Performance Plan for options granted by the Company:

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2006	819,549	$3.97
Granted	100,000	$1.00
Terminated	(134,600)	$3.58
Exercised	—	$ —
Outstanding at December 31, 2007	784,949	$3.66
Granted	475,000	$0.79
Expired	(131,000)	$2.96
Terminated	(1,700)	$3.79
Exercised	—	$ —
Outstanding at December 31, 2008	1,127,249	$2.55

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.50 - $0.65	325,000	9.7	$0.60	175,000	$0.56
$1.00	100,000	8.6	$1.00	100,000	$1.00
$1.20	150,000	9.7	$1.20	—	—
$1.35 - $2.40	175,900	4.6	$1.78	175,900	$1.78
$4.35 - $4.91	160,000	6.5	$4.37	155,000	$4.37
$5.20 - $7.12	216,349	2.2	$6.33	216,349	$6.33
	1,127,249	6.9	$2.53	822,249	$3.11

The aggregate intrinsic value for the outstanding and exercisable in-the-money options was $1,000 at December 31, 2008.

A summary of the status of the Company's non-vested options as of December 31, 2008 and changes during the year ended December 31, 2008 is presented below:

Non-vested Options	Number of Shares	Weighted Average Grant-date Fair Value
Outstanding at December 31, 2007	110,463	$2.83
Granted	475,000	$0.47
Vested	(280,463)	$1.30
Terminated	—	—
Exercised	—	—
Outstanding at December 31, 2008	305,000	$0.52

As of December 31, 2008, there was $98,000 of unrecognized compensation costs, based on the fair value of unvested awards, related to non-vested share-based compensation arrangements granted under the Performance Plan. This cost is expected to be recognized over a weighted average period of 0.4 years. No windfall tax benefits were recognized during the years ended December 31, 2008 or 2007.

13 SEGMENT INFORMATION

The Company's management reviews financial information, allocates resources and manages its business by geographic region. The Domestic region, which includes corporate expenditures, contains the Company's subsidiaries in the United States. The Italian region contains the Company's subsidiary located in Italy. The information provided is based on internal reports and was developed and utilized by management for the sole purpose of tracking trends and changes in the results of the regions. The information, including the allocations of expense and overhead, was calculated based on a management approach and may not reflect the actual economic costs, contributions or results of operations of the regions as stand-alone businesses. If a different basis of presentation or allocation were utilized, the relative contributions of the regions might differ but the relative trends would, in management's view, likely not be materially impacted. The table below sets forth net revenues, income (loss) from operations, total assets and goodwill by region for the years ended December 31, 2008 and 2007:

	Domestic	Italian	Eliminations	Total
December 31, 2008:				
External net sales	$14,262,569	$ 6,556,606	$ —	$ 20,819,175
Intercompany sales	873,094	180,321	(1,053,415)	—
Net revenue	$15,135,663	$ 6,736,927	$(1,053,415)	$ 20,819,175
Loss from operations	$ (61,196)	$ (174,450)	$ (7,380)	$ (243,026)
Assets	$14,578,460	$ 8,469,608	$ —	$ 23,048,068
Goodwill	$ 870,290	$ —	$ —	$ 870,290
December 31, 2007:				
External net sales	$13,726,958	$ 6,248,912	$ —	$ 19,975,870
Intercompany sales	858,921	445,171	(1,304,092)	—
Net revenue	$14,585,879	$ 6,694,083	$(1,304,092)	$ 19,975,870
Loss from operations	$(1,998,668)	$(9,304,074)	$ (14,856)	$(11,317,598)
Assets	$16,270,801	$ 9,497,531	$ —	$ 25,768,332
Goodwill	$ 870,290	$ —	$ —	$ 870,290

14 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, 2008 and 2007 totaled $544,000 and $614,000, respectively. The future minimum lease payments under non-cancelable capital leases and their related assets recorded at December 31, 2008 and 2007 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, 2008 were as follows:

2009	$ 467,000
2010	443,000
2011	360,000
2012	287,000
2013	280,000
Thereafter	—
Total minimum lease payments	$1,837,000

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.

15 QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following table summarizes selected quarterly data of the Company for the years ended December 31, 2008 and 2007 (in thousands except per share data):

2008	First Quarter	Second Quarter	Third Quarter[1][2]	Fourth Quarter[3]	Full Year
Net revenue	$5,242	$5,363	$ 5,417	$ 4,797	$ 20,819
Gross profit	3,217	3,226	3,244	2,744	12,431
Income (loss) from operations	183	295	6	(727)	(243)
Net income (loss)	345	297	19	(465)	196
Basic and diluted net income (loss) per share	0.01	0.01	0.00	(0.02)	0.01
2007					
Net revenue	$4,946	$5,121	$ 4,972	$ 4,937	$ 19,976
Gross profit	2,988	2,980	2,762	2,846	11,576
Loss from operations	(292)	(580)	(8,391)	(2,055)	(11,318)
Net loss	(238)	(463)	(7,841)	(1,892)	(10,434)
Basic and diluted net loss per share	(0.01)	(0.02)	(0.28)	(0.07)	(0.38)

(1) In 2007, includes the effect of the write-off of certain PARSEC® related assets, as discussed in Note 3, *Write-off of Certain PARSEC® Assets.*

(2) In 2007, includes the effect of the write-off of goodwill relating to both Delta Biologicals and ImmunoVision, as discussed in Note 4, *Impairment of Long-Lived Assets Including Goodwill.*

(3) In 2008, includes the effect of the write-off of a portion of the Company's product license of hepatitis technology, as discussed in Note 5, *Product License, Including Impairment Charge.* In 2007, includes the effect of severance costs, as discussed in Note 6, *Severance Costs.*

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 loss per share amounts due to the effects of rounding.

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

None.

ITEM 9A(T). CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

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

Management's Report on Internal Control over Financial Reporting

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

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

As of the end of the period covered by this Annual Report on Form 10-K, our management evaluated, with the participation of our principal executive officer and principal financial officer, the effectiveness of our internal control over financial reporting. This evaluation was conducted using the framework in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based upon that evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2008.

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

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding our internal control over financial reporting. Our management's report on internal control over financial reporting was not subject to attestation by our independent registered public

accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit us to provide only our management's report on internal control over financial reporting in this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2008 that would have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On March 27, 2009, we entered into an employment agreement with Dr. Charles R. Struby, our Chief Executive Officer and President. Dr. Struby's employment agreement has an initial term of three years and will automatically renew for successive one year periods unless either Dr. Struby or we exercise the option to allow the employment agreement to expire at the end of the then-current term. Under the employment agreement, Dr. Struby will be paid an initial annual base salary of $250,000, and we will review Dr. Struby's base salary at least annually. In addition, under the terms and condition of the employment agreement, Dr. Struby received a signing bonus of $25,000 and options to purchase 100,000 shares of our common stock under our 1999 Performance Equity Plan at an exercise price of $0.37 per share, which equaled the closing price of our common stock on the AMEX on March 27, 2009. These options fully vested as of March 27, 2009 and will expire on March 26, 2019. The employment agreement also provides that Dr. Struby will be eligible to receive, among other things, an annual cash bonus upon the achievement of financial performance targets under any annual cash incentive program in effect from time to time or otherwise in the discretion of the Board or the Compensation Committee. In addition, under the employment agreement, we are required to reimburse Dr. Struby for certain enumerated expenses related to the relocation of his primary residence to Palm Beach, Broward, Miami-Dade or Monroe County, Florida, up to an aggregate of $100,000, and we are required to reimburse him for other business expenses in accordance with our policies and procedures for expense reimbursement. Upon the termination of the employment agreement by us with "Cause" (as defined in the employment agreement) or upon Dr. Struby's resignation other than for "Good Reason" (as defined in the employment agreement), Dr. Struby will be entitled to receive all base salary compensation which has been fully earned but has not yet been paid to him, and all of Dr. Struby's unvested equity-based awards will be forfeited. Upon the expiration of the employment agreement as a result of either our or Dr. Struby's election to allow the employment agreement to expire at the end of the then-current term, Dr. Struby will be entitled to receive or be reimbursed for, as the case may be, all base salary and annual cash bonus compensation which has been fully earned but has not yet been paid to him and all relocation and business expenses incurred by him which has not yet been reimbursed (such compensation, collectively, the "Struby Accrued Compensation"). Upon the termination of the employment agreement by us without "Cause" or as a result of Dr. Struby's "Disability" (as defined in the employment agreement) or death, or upon Dr. Struby's resignation for "Good Reason," including, without limitation, as a result of a "Change in Control" (as defined in the employment agreement) during the initial three-year term of the employment agreement, Dr. Struby or his estate, as the case may be, will be entitled to receive the Struby Accrued Compensation and a one-time lump sum payment in an amount equal to Dr. Struby's then-current base salary. In addition, in the event we terminate the employment agreement without "Cause," the employment agreement is terminated as a result of Dr. Struby's "Disability" or Dr. Struby resigns for "Good Reason," including, without limitation, as a result of a "Change in Control" during the initial three-year term of the employment agreement, we, at our sole expense, will maintain in full force and effect for a period of twelve months for the continued benefit of Dr. Struby and his spouse and dependents all welfare benefit plans and programs, including, without limitation, medical, dental, disability and accidental death and dismemberment plans and programs, in which Dr. Struby or his spouse or dependents were participating, and we, at our sole expense, will continue Dr. Struby's and his spouse's and dependents' medical coverage for a period ending upon the earlier of the one year anniversary of the termination of the employment agreement and such time as Dr. Struby becomes covered by another employer group health plan or by Medicare. The employment agreement also includes non-disclosure, non-solicitation, anti-raiding and non-disparagement covenants by Dr. Struby.

In addition, on March 27, 2009, we entered into an employment agreement with Kevin D. Clark, our Chief Operating Officer and the Chief Operating Officer of ImmunoVision. Mr. Clark's employment agreement has an initial term of three years and will automatically renew for successive one year periods unless either Mr. Clark or we exercise the option to allow the employment agreement to expire at the end of the then-current term. Under the employment agreement, Mr. Clark will be paid an initial annual base salary of $227,000, and we will review Mr. Clark's base salary at least annually. The employment agreement also provides that Mr. Clark will be eligible to receive, among other things, equity compensation under our equity compensation plans and an annual cash bonus upon the achievement of financial performance targets under any annual cash incentive program in effect from time to time or otherwise in the discretion of the Board or the Compensation Committee. In addition, under the employment agreement, we are required to reimburse Mr. Clark for business expenses incurred by him in accordance with our policies and procedures for expense reimbursement. Upon the termination of the employment agreement by us with "Cause" (as defined in the employment agreement) or upon Mr. Clark's resignation other than for "Good Reason" (as defined in the employment agreement), Mr. Clark will be entitled to receive all base salary compensation which has been fully earned but has not yet been paid to him, and all of Mr. Clark's unvested equity-based awards will be forfeited. Upon the expiration of the employment agreement as a result of either our or Mr. Clark's election to allow the employment agreement to expire at the end of the then-current term, Mr. Clark will be entitled to receive or be reimbursed for, as the case may be, all base salary and annual cash bonus compensation which has been fully earned but has not yet been paid to him and all business expenses incurred by him which has not yet been reimbursed (such compensation, collectively, the "Clark Accrued Compensation"). Upon the termination of the employment agreement by us without "Cause" or as a result of Mr. Clark's "Disability" (as defined in the employment agreement) or death, or upon Mr. Clark's resignation for "Good Reason," including, without limitation, as a result of a "Change in Control" (as defined in the employment agreement) during the initial three-year term of the employment agreement, Mr. Clark or his estate, as the case may be, will be entitled to receive the Clark Accrued Compensation and a one-time lump sum payment in an amount equal to Mr. Clark's then-current base salary. In addition, in the event we terminate the employment agreement without "Cause," the employment agreement is terminated as a result of Mr. Clark's "Disability" or Mr. Clark resigns for "Good Reason," including, without limitation, as a result of a "Change in Control" during the initial three-year term of the employment agreement, we, at our sole expense, will maintain in full force and effect for the continued benefit of Mr. Clark and his spouse and dependents for a period of twelve months all welfare benefit plans and programs, including, without limitation, medical, dental, disability and accidental death and dismemberment plans and programs, in which Mr. Clark or his spouse or dependents were participating, and we, at our sole expense, will continue Mr. Clark's and his spouse's and dependents' medical coverage for a period ending upon the earlier of the one year anniversary of the termination of the employment agreement and such time as Mr. Clark becomes covered by another employer group health plan or by Medicare. The employment agreement also includes non-disclosure, non-solicitation, anti-raiding and non-disparagement covenants by Mr. Clark.

The foregoing description of the employment agreements of Dr. Struby and Mr. Clark, as well as all other descriptions of such employment agreements contained herein, are qualified in their entirety by reference to the full text of the employment agreements, copies of which are filed herewith as Exhibits 10.3 and 10.4, respectively, and are incorporated by reference herein.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

The following table sets forth information with respect to our directors and our executive officers as of March 27, 2009.

Name	Age	Position
Charles R. Struby, Ph.D.	59	Chief Executive Officer and President
Kevin D. Clark	46	Chief Operating Officer
Duane M. Steele	58	Vice President—Business Development
Mark S. Deutsch	46	Chief Financial Officer and Vice President—Finance
Patrice R. Debregeas	65	Chairman of the Board of Directors
Paul F. Kennedy	64	Director
Jerry C. Benjamin	68	Director
John B. Harley, M.D., Ph.D.	59	Director
Laurent Le Portz	42	Director
Lawrence G. Meyer	68	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 27, 2009. 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.

Dr. Charles R. Struby, age 59, was appointed our Chief Executive Officer and President in January 2009. Dr. Struby has over 25 years of senior executive experience in the life sciences industry. Most recently, Dr. Struby served as Senior Director of Business Development of The Medicines Company, a NASDAQ-listed acute-care pharmaceutical company, from 2006 through 2008. From 2005 through 2006, Dr. Struby served as General Manager of Kansas City Operations of Harte-Hanks, Inc., a worldwide direct and targeted marketing company, and as Vice President of The Mattson Jack Group, Inc., a consulting firm focused on the pharmaceutical and biotech industries. From 1982 through 2004, Dr. Struby served Sanofi-Aventis Pharmaceuticals, Inc. (and its legacy companies), a leading global pharmaceutical company, in a variety of senior executive positions, including various director and vice president positions. Prior to that time, Dr. Struby practiced as a certified public accountant. Dr. Struby earned his B.S. in Business from Kansas State University, his M.S. in Accounting from Louisiana State University and his Ph.D. in Pharmaceutical Sciences from the University of Missouri at Kansas City.

Mr. Kevin D. Clark, age 46, has served as our Chief Operating Officer since September 2007 and as Chief Operating Officer of ImmunoVision since 1987. Mr. Clark served as our acting Chief Executive Officer from January 2008 to September 2008. He also served as President of ImmunoVision from 1987 through 1995. Mr. Clark was a founding member of the Arkansas Biotech Association and, from 1995 through 2004, served as its Executive Vice President, and in 2002, served as its President. Since 2003, Mr. Clark has served as a member of the Executive Committee of the University of Arkansas Technology Development Foundation, a non-profit foundation for the commercialization of technology developed at the University of Arkansas in Fayetteville. From 2000 to 2003, Mr. Clark was a member of the Advisory Board of Arkansas BioVentures, a state and federally funded incubator program for biotechnology.

Mr. Duane M. Steele, age 58, has served as our Vice President—Business Development since the merger with the pre-merger IVAX Diagnostics in 2001 and had served in the same capacity with the pre-merger IVAX

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

Mr. Mark S. Deutsch, age 46, has served as our Chief Financial Officer and Vice President—Finance since the merger with the pre-merger IVAX Diagnostics in 2001 and had served in the same capacities with the pre-merger IVAX Diagnostics since 1996. He has served as the Vice President—Finance of Diamedix since 1993 and has 15 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.

Mr. Patrice R. Debregeas, age 65, has served as the Chairman of our Board of Directors since January 2009 and as a director since September 2008. Mr. Debregeas served as the Vice Chairman of our Board of Directors from September 2008 to January 2009. Mr. Debregeas has served as President of Debregeas & Associes Pharma SAS, a company specializing in drug development located in Paris, France, since 2006. From 1977 through 2005, Mr. Debregeas served as Chief Executive Officer and President of Ethypharm SA, a company co-founded by Mr. Debregeas which is a leader in the field of drug delivery in Europe.

Mr. Paul F. Kennedy, age 64, has served as a director since September 2008. From September 2008 to January 2009, Mr. Kennedy served as the Chairman of our Board of Directors and as our Chief Executive Officer and President. Mr. Kennedy has more than 30 years of senior executive experience in the life sciences industry. Most recently, Mr. Kennedy served as President of International Operations of Cozart plc, a medical diagnostics company specializing in drugs-of-abuse testing in the U.K. and Europe, from 2004 through 2007, and as Executive Director of Cozart from 2005 through 2007. Prior to joining Cozart, Mr. Kennedy worked as an independent consultant primarily in merger and acquisition activity in the healthcare industry from 1999 through 2004. In addition, from 1979 through 1994, Mr. Kennedy served as Chief Executive Officer and President of Novo Nordisk France, a French subsidiary of the world's leading pharmaceutical company in the insulin market.

Mr. Jerry C. Benjamin, age 68, has served as a director since October 2008. Since 1985, Mr. Benjamin has been a General Partner of Advent Venture Partners, a venture capital management firm located London which focuses on venture and growth investment in the life sciences and technology industries. Mr. Benjamin serves on the boards of directors of Orthofix International N.V., a multinational corporation principally involved in the design, development, manufacture, marketing and distribution of medical devices, principally for the orthopedic products market, and Micromet, Inc., a biopharmaceutical company developing novel, proprietary antibodies for the treatment of cancer, inflammation and autoimmune diseases. Mr. Benjamin has served on the boards of directors of over 35 public and private companies within the life sciences industry.

Dr. John B. Harley, age 59, has served as a director since the merger with the pre-merger IVAX Diagnostics in 2001. He has held various positions at the University of Oklahoma Health Sciences Center since 1982. In the Department of Medicine, his positions include Chief of Rheumatology, Allergy and Immunology Section (1999 to present), James R. McEldowney Chair in Immunology and Professor of Medicine (1992 to 2007), Vice Chair for Research, George Lynn Cross Research Professor (1992 to 2004), Associate Professor (1986 to 1992) and Assistant Professor (1982 to 1986). Since 1996, Dr. Harley has been an Adjunct Professor in the Department of Pathology. In the Department of Microbiology, Dr. Harley has served as Adjunct Professor (1992 to present), Adjunct Associate Professor (1988 to 1992) and Adjunct Assistant Professor (1983 to 1988). Since 1982, Dr. Harley has also been associated with the Oklahoma Medical Research Foundation's Arthritis and Immunology Program as Program Head (1999 to present), Member (1998 to present), Associate Member (1989 to present), Affiliated Associate Member (1986 to 1989) and Affiliated Assistant Member (1982 to 1986). Dr. Harley has also served as a Staff Physician (1982, 1984 to 1987 and 1992 to present) and a Clinical Investigator (1987 to 1992), Immunology Section, Medical Service at the Veterans Affairs Medical Center,

Oklahoma City, Oklahoma. In 1981 and 1982, Dr. Harley was a Postdoctoral Fellow in Rheumatology with the Arthritis Branch of the National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases, National Institute of Health, Bethesda, Maryland. He was also a Clinical Associate at the Laboratory of Immunoregulation, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland from 1979 to 1982. Dr. Harley is also the Secretary and a member of the Board of Directors of JK Autoimmunity, Inc., as well as the Secretary and Treasurer and a member of the Boards of Directors of Dynamic Ventures, Inc. and VRB Associates, Inc.

Mr. Laurent Le Portz, age 42, has served as a director since September 2008. Since November, 2008, Mr. Le Portz has been a Partner of ArMen Capital Management, an investment management company focused on investments in public and private securities and advising companies on financing and structuring issues. From 2007 to October, 2008, Mr. Le Portz served as a Director of Fin'active, an investment management company focused on making controlling investments in diverse industries with an aim towards balance sheet rejuvenation, operational restricting and strategic refocus. Prior to that time, Mr. Le Portz served as Chief Executive Officer of Ethypharm North America, the North American operating subsidiary of Ethypharm SA, as well as Chief Financial Officer of Mojave Therapeutics, a biotechnology company which specialized in the development of off-the-shelf products for the treatment of cancer and viral diseases. Mr. Le Portz received an M.B.A. from Harvard Business School and an M.S. in Mathematics from Ecole Polytechnique in France.

Mr. Lawrence G. Meyer, age 68, has served as a director since October 2008. Mr. Meyer has been a practicing attorney for over 35 years and is currently the owner of The Law Offices of Lawrence G. Meyer. Prior to opening his own law offices, Mr. Meyer was a partner at Gadsby Hannah LLP, Arent Fox LLP and Patton Boggs LLP. Prior to entering the private practice of law, Mr. Meyer was the Director of the Office of Policy Planning and Evaluation of the Federal Trade Commission, had served as legislative assistant and legal counsel to U.S. Senator Robert P. Griffin and was an attorney with the U.S. Department of Justice. He has served as a director of the Hockey Hall of Fame in Toronto, Canada and small development pharmaceutical firms.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires our directors, executive officers and 10% stockholders to file initial reports of ownership and reports of changes in ownership of our common stock and other equity securities with the Securities and Exchange Commission and the American Stock Exchange. Our directors, executive officers and 10% stockholders are required to furnish us with copies of all Section 16(a) reports they file. Based on a review of the copies of such reports furnished to us and written representations from our directors and executive officers that no other reports were required, we believe that our directors, executive officers and 10% stockholders complied with all Section 16(a) filing requirements applicable to them for the year ended December 31, 2008.

Code of Conduct and Ethics

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

Audit Committee Members and Financial Expert

The members of the Audit Committee of our Board of Directors are Jerry C. Benjamin, Laurent Le Portz and Lawrence G. Meyer. Our Board of Directors has determined that each of Messrs. Benjamin and Le Portz has the attributes, education and experience of, and therefore is, an "audit committee financial expert," as such term is defined in Item 407(d)(5) of Regulation S-K, and that each of Messrs. Benjamin and Le Portz is "independent," as such term is defined in the applicable regulations of the Securities and Exchange Commission and rules of the American Stock Exchange relating to directors serving on audit committees.

ITEM 11. EXECUTIVE COMPENSATION

Compensation of Named Executive Officers

Summary Compensation Table—2008

The following table sets forth certain summary information concerning compensation which, during the fiscal years ended December 31, 2008 and 2007, we paid or accrued to or on behalf of each individual serving or acting as our principal executive officer during the fiscal year ended December 31, 2008, and each of the two most highly compensated executive officers (other than the aforementioned individuals) serving as executive officers at the end of the year ended December 31, 2008 (collectively, the "Named Executive Officers").

Name and Principal Position	Year	Salary	Bonus	Stock Awards	Option Awards[5]	Non-Equity Incentive Plan Compensation[6]	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Charles R. Struby, Ph.D.,[1]	2008	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Chief Executive Officer	2007	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Paul F. Kennedy,[2]	2008	$ 83,334	—	—	—	—	—	$ 16,666	$100,000
Former Chief Executive Officer	2007	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Kevin D. Clark,[3]	2008	$227,000	—	—	$16,480	$146,833	—	—	$390,313
Chief Operating Officer and Former Acting Chief Executive Officer	2007	$128,784	—	—	—	—	—	—	$128,784
Giorgio D'Urso,[4]	2008	$ 12,064	—	—	—	—	—	—	$ 12,064
Former Chief Executive Officer	2007	$348,519	—	—	—	—	—	$495,000	$843,519
Duane M. Steele,	2008	$219,752	—	—	$16,480	$163,149	—	—	$399,381
Vice President—Business Development	2007	$216,888	—	—	$10,587	—	—	—	$227,475
Mark S. Deutsch,	2008	$151,500	—	—	$16,480	$109,083	—	—	$277,063
Chief Financial Officer	2007	$128,625	—	—	$ 4,636	—	—	—	$133,261

(1) Dr. Struby was appointed our Chief Executive Officer and President on January 23, 2009. Prior to that date, Dr. Struby was not employed by us. Accordingly, pursuant to the rules and regulations of the Securities and Exchange Commission, no compensation information is set forth with respect to Dr. Struby. On March 27, 2009, Dr. Struby entered into an employment agreement with us, the terms of which are described under "Potential Payments upon Termination or Change-in-Control" below and under "Item 9B. Other Information."

(2) Mr. Kennedy served as our Chief Executive Officer, President and Chairman of the Board of Directors from September 23, 2008 until his resignation from such positions on January 23, 2009. Other than during that four month period, Mr. Kennedy has not been employed by us. Accordingly, pursuant to the rules and regulations of the Securities and Exchange Commission, the compensation information set forth with respect to Mr. Kennedy includes only compensation paid or accrued by us to or on behalf of Mr. Kennedy for his services during that four month period. In connection with his resignation as our Chief Executive Officer, President and Chairman of the Board of Directors, we

and Mr. Kennedy entered into a separation agreement and release on March 27, 2009, pursuant to which we agreed to pay Mr. Kennedy a one time lump-sum payment of $100,000, $83,334 of which relates to base salary compensation for Mr. Kennedy's services during the four month period and the remaining $16,666 of which is consideration for Mr. Kennedy's execution of the separation agreement and release. The terms of Mr. Kennedy's separation agreement and release with us are described in further detail below under "Potential Payments upon Termination or Change-in-Control." Mr. Kennedy continues to serve as a member of our Board of Directors.

(3) Mr. Clark was appointed our Chief Operating Officer on September 17, 2007, and continues to serve in that position. Mr. Clark served as our acting Chief Executive Officer from January 10, 2008 through September 22, 2008. Throughout the fiscal year ended December 31, 2007, Mr. Clark served as, and Mr. Clark continues to serve as, the Chief Operating Officer of ImmunoVision. Accordingly, pursuant to the rules and regulations of the Securities and Exchange Commission, the compensation information set forth with respect to Mr. Clark includes (a) for the period from January 1, 2007 through September 16, 2007, compensation paid or accrued by us to or on behalf of Mr. Clark for his services as Chief Operating Officer of ImmunoVision, (b) for the period from September 17, 2007 through January 9, 2008, compensation paid or accrued by us to or on behalf of Mr. Clark for his services as our Chief Operating Officer and as Chief Operating Officer of ImmunoVision, (c) for the period from January 10, 2008 through September 22, 2008, compensation paid or accrued by us to or on behalf of Mr. Clark for his services as our acting Chief Executive Officer and our Chief Operating Officer and as Chief Operating Officer of ImmunoVision, and (d) for the period from September 23, 2008 through December 31, 2008, compensation paid or accrued by us to or on behalf of Mr. Clark for his services as our Chief Operating Officer and as Chief Operating Officer of ImmunoVision. On March 27, 2009, Mr. Clark entered into an employment agreement with us, the terms of which are described under "Potential Payments upon Termination or Change-in-Control" below and under "Item 9B. Other Information."

(4) Mr. D'Urso served as our Chief Executive Officer and President until his resignation from such positions, effective January 10, 2008. Mr. D'Urso was party to an employment agreement which provided for him to serve as our Chief Executive Officer and President until February 24, 2010 and to receive a minimum annual base salary of $348,519. In connection with Mr. D'Urso's resignation as our Chief Executive Officer and President, effective January 10, 2008, we and Mr. D'Urso mutually agreed to terminate his employment agreement and entered into a separation agreement and mutual release, pursuant to which we paid Mr. D'Urso a one time lump-sum payment of $495,000. Accordingly, the $495,000 set forth under the "All Other Compensation" column for 2007 represents the amount accrued by us during the year ended December 31, 2007 in connection with the payments and reimbursements made or then to be made by us to Mr. D'Urso under the separation agreement and mutual release between us and Mr. D'Urso. The terms of Mr. D'Urso's employment agreement and the separation agreement and general release between us and Mr. D'Urso are described in further detail below under "Potential Payments upon Termination or Change-in-Control."

(5) Represents the dollar amount recognized for financial statement reporting purposes for the fiscal year ended December 31, 2008, in accordance with FAS 123(R), without taking into account an estimate of forfeitures related to service-based vesting, of stock option grants, including amounts from awards granted prior to 2008. Assumptions used in the calculation of these amounts are included in Note 12 to our Consolidated Financial Statements, *Shareholders' Equity*. There were no forfeitures during 2008. The amount also includes the effect of a cumulative effect adjustment recorded as a result of the change in classification of certain stock options to a liability award grant in accordance with FAS 123(R), as well as fair value adjustments that occurred during the fiscal year ended December 31, 2008 to that liability award.

(6) The amounts for 2008 are comprised of payments made under a retention bonus plan to Messrs. Clark, Steele and Deutsch in connection with the September 2, 2008 acquisition by the Debregeas – Kennedy Group of approximately 72.3% of the outstanding shares of our common stock from Teva as follows: Mr. Clark—$113,500; Mr. Steele—$109,876; and Mr. Deutsch—$75,750. Each 2008 amount is also comprised of $33,333 which was paid to Messrs. Clark, Steele and Deutsch under our executive officer incentive plan for the year ended December 31, 2008 upon the achievement of pre-established operating income goals. In addition, the amount for 2008 for Mr. Steele includes $19,940 earned by Mr. Steele during 2008 under an executive officer incentive plan pursuant to which Mr. Steele was entitled to receive an amount equal to 2% of the increase in Diamedix's audited operating income from the year ended December 31, 2007 to the year ended December 31, 2008, excluding, for the purposes of this calculation, one-time non-recurring adjustments and extraordinary items.

Outstanding Equity Awards at Fiscal Year-End—2008

The following table sets forth certain information regarding equity-based awards held by the Named Executive Officers as of December 31, 2008.

	Option Awards				
Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price	Option Expiration Date
Charles R. Struby, Ph.D.[1]	N/A	N/A	N/A	N/A	N/A
Paul F. Kennedy	—	—	—	—	—
Kevin D. Clark	—	50,000[2]	—	$0.65	9/22/18
	—	50,000[3]	—	$1.20	9/22/18
Giorgio D'Urso	—	—	—	—	—
Duane M. Steele	10,233	—	—	$7.12	3/17/11
	10,000	—	—	$4.35	7/13/15
	—	50,000[2]	—	$0.65	9/22/18
	—	50,000[3]	—	$1.20	9/22/18
Mark S. Deutsch	5,116	—	—	$7.12	3/17/11
	10,000	—	—	$4.35	7/13/15
	—	50,000[2]	—	$0.65	9/22/18
	—	50,000[3]	—	$1.20	9/22/18

(1) As of December 31, 2008, Dr. Struby did not hold any options to purchase shares of our common stock. On March 27, 2009, Dr. Struby entered into an employment agreement with us, pursuant to which, among other things, Dr. Struby was granted options to purchase 100,000 shares of our common stock under our 1999 Performance Equity Plan at an exercise price of $0.37 per share, which equaled the closing price of our common stock on the AMEX on March 27, 2009. These options fully vested as of March 27, 2009 and will expire on March 26, 2019. The additional terms of Dr. Struby's employment agreement with us are described under "Potential Payments upon Termination or Change-in-Control" below and under "Item 9B. Other Information."

(2) These options vested on March 23, 2009, but they are included as unexercisable options because they were not exercisable as of December 31, 2008. As a result of their vesting on March 23, 2009, these options are currently exercisable.

(3) Vests on March 23, 2010.

Potential Payments upon Termination or Change-in-Control

On March 27, 2009, we entered into an employment agreement with Charles R. Struby, Ph.D., our Chief Executive Officer and President. The employment agreement has an initial term of three years and will automatically renew for successive one year periods unless either Dr. Struby or we exercise the option to allow the employment agreement to expire at the end of the then-current term. Under the employment agreement, Dr. Struby will be paid an initial annual base salary of $250,000, and we will review Dr. Struby's base salary at least annually. The employment agreement also provides that Dr. Struby will be eligible to receive, among other things, an annual cash bonus upon the achievement of financial performance targets under any annual cash

incentive program in effect from time to time or otherwise in the discretion of the Board or the Compensation Committee. In addition, under the employment agreement, we are required to reimburse Dr. Struby for certain enumerated expenses related to the relocation of his primary residence to Palm Beach, Broward, Miami-Dade or Monroe County, Florida, up to an aggregate of $100,000, and we are required to reimburse him for other business expenses in accordance with our policies and procedures for expense reimbursement. Upon the termination of the employment agreement by us with "Cause" (as defined in the employment agreement) or upon Dr. Struby's resignation other than for "Good Reason" (as defined in the employment agreement), Dr. Struby will be entitled to receive all base salary compensation which has been fully earned but has not yet been paid to him, and all of Dr. Struby's unvested equity-based awards will be forfeited. Upon the expiration of the employment agreement as a result of either our or Dr. Struby's election to allow the employment agreement to expire at the end of the then-current term, Dr. Struby will be entitled to receive or be reimbursed for, as the case may be, all base salary and annual cash bonus compensation which has been fully earned but has not yet been paid to him and all relocation and business expenses incurred by him which has not yet been reimbursed (such compensation, collectively, the "Struby Accrued Compensation"). Upon the termination of the employment agreement by us without "Cause" or as a result of Dr. Struby's "Disability" (as defined in the employment agreement) or death, or upon Dr. Struby's resignation for "Good Reason," including, without limitation, as a result of a "Change in Control" (as defined in the employment agreement) during the initial three-year term of the employment agreement, Dr. Struby or his estate, as the case may be, will be entitled to receive the Struby Accrued Compensation and a one-time lump sum payment in an amount equal to Dr. Struby's then-current base salary. In addition, in the event we terminate the employment agreement without "Cause," the employment agreement is terminated as a result of Dr. Struby's "Disability" or Dr. Struby resigns for "Good Reason," including, without limitation, as a result of a "Change in Control" during the initial three-year term of the employment agreement, we, at our sole expense, will maintain in full force and effect for a period of twelve months for the continued benefit of Dr. Struby and his spouse and dependents all welfare benefit plans and programs, including, without limitation, medical, dental, disability and accidental death and dismemberment plans and programs, in which Dr. Struby or his spouse or dependents were participating, and we, at our sole expense, will continue Dr. Struby's and his spouse's and dependents' medical coverage for a period ending upon the earlier of the one year anniversary of the termination of the employment agreement and such time as Dr. Struby becomes covered by another employer group health plan or by Medicare. The employment agreement also includes non-disclosure, non-solicitation, anti-raiding and non-disparagement covenants by Dr. Struby. See "Item 9B. Other Information" for a discussion of certain other terms and conditions of Dr. Struby's employment agreement with us.

On March 27, 2009, we entered into an employment agreement with Kevin D. Clark, our Chief Operating Officer. The employment agreement has an initial term of three years and will automatically renew for successive one year periods unless either Mr. Clark or we exercise the option to allow the employment agreement to expire at the end of the then-current term. Under the employment agreement, Mr. Clark will be paid an initial annual base salary of $227,000, and we will review Mr. Clark's base salary at least annually. The employment agreement also provides that Mr. Clark will be eligible to receive, among other things, equity compensation under our equity compensation plans and an annual cash bonus upon the achievement of financial performance targets under any annual cash incentive program in effect from time to time or otherwise in the discretion of the Board or the Compensation Committee. In addition, under the employment agreement, we are required to reimburse Mr. Clark for business expenses incurred by him in accordance with our policies and procedures for expense reimbursement. Upon the termination of the employment agreement by us with "Cause" (as defined in the employment agreement) or upon Mr. Clark's resignation other than for "Good Reason" (as defined in the employment agreement), Mr. Clark will be entitled to receive all base salary compensation which has been fully earned but has not yet been paid to him, and all of Mr. Clark's unvested equity-based awards will be forfeited. Upon the expiration of the employment agreement as a result of either our or Mr. Clark's election to allow the employment agreement to expire at the end of the then-current term, Mr. Clark will be entitled to receive or be reimbursed for, as the case may be, all base salary and annual cash bonus compensation which has been fully earned but has not yet been paid to him and all business expenses incurred by him which has not yet been reimbursed (such compensation, collectively, the "Clark Accrued Compensation"). Upon the termination of the

employment agreement by us without "Cause" or as a result of Mr. Clark's "Disability" (as defined in the employment agreement) or death, or upon Mr. Clark's resignation for "Good Reason," including, without limitation, as a result of a "Change in Control" (as defined in the employment agreement) during the initial three-year term of the employment agreement, Mr. Clark or his estate, as the case may be, will be entitled to receive the Clark Accrued Compensation and a one-time lump sum payment in an amount equal to Mr. Clark's then-current base salary. In addition, in the event we terminate the employment agreement without "Cause," the employment agreement is terminated as a result of Mr. Clark's "Disability" or Mr. Clark resigns for "Good Reason," including, without limitation, as a result of a "Change in Control" during the initial three-year term of the employment agreement, we, at our sole expense, will maintain in full force and effect for the continued benefit of Mr. Clark and his spouse and dependents for a period of twelve months all welfare benefit plans and programs, including, without limitation, medical, dental, disability and accidental death and dismemberment plans and programs, in which Mr. Clark or his spouse or dependents were participating, and we, at our sole expense, will continue Mr. Clark's and his spouse's and dependents' medical coverage for a period ending upon the earlier of the one year anniversary of the termination of the employment agreement and such time as Mr. Clark becomes covered by another employer group health plan or by Medicare. The employment agreement also includes non-disclosure, non-solicitation, anti-raiding and non-disparagement covenants by Mr. Clark.

In connection with Paul F. Kennedy's resignation as our Chief Executive Officer, President and Chairman of our Board of Directors on January 23, 2009, we and Mr. Kennedy entered into a separation agreement and release on March 27, 2009, pursuant to which we agreed to pay Mr. Kennedy a one time lump-sum payment of $100,000, $83,334 of which relates to base salary compensation for Mr. Kennedy's services as our Chief Executive Officer, President and Chairman of the Board of Directors during the four month period commencing on September 23, 2008, the date on which he was appointed to such positions, and ending on January 23, 2009, the date on which he resigned from such positions, and the remaining $16,666 of which is consideration for Mr. Kennedy's execution of the separation agreement and general release. Our obligation to make such one time lump-sum payment to Mr. Kennedy is conditioned upon, among other things, Mr. Kennedy selling at least 1.5 million shares of our common stock to Patrice Debregeas and/or Mr. Debregeas' affiliates. In addition to the $100,000 one time lump-sum payment, under the terms and conditions of the separation agreement and release, we are required to reimburse Mr. Kennedy for up to $22,000 of expenses incurred by Mr. Kennedy in connection with his service as our Chief Executive Officer, President and Chairman of the Board of Directors. The separation agreement and release also contains a mutual release by and between us and Mr. Kennedy. The separation agreement and release has no impact on Mr. Kennedy's service as a member of our Board of Directors.

On October 1, 1998, the pre-merger IVAX Diagnostics entered into a five-year employment agreement with Giorgio D'Urso, our former Chief Executive Officer and President, at a base annual salary of $348,519, with discretionary annual adjustments. We assumed this employment agreement in the merger of the pre-merger IVAX Diagnostics with b2bstores.com, Inc. We previously extended the term of Mr. D'Urso's employment agreement until February 24, 2010. Pursuant to the terms and conditions of this employment agreement, we were permitted to terminate Mr. D'Urso's employment with or without cause at any time upon written notice. For a termination without cause, we would have been required to pay Mr. D'Urso his then current annual base salary in installments for the remainder of the employment term. This employment agreement further provided that, while employed by us and for a two-year period thereafter, Mr. D'Urso would not be permitted to employ or contract with any of our current or former employees, except former employees who have not been employed by us for more than one year.

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

Compensation of Directors

The Compensation Committee of the Board recommends director compensation to the Board, and the Board approves director compensation, based on factors it considers appropriate, market conditions and trends and the recommendations of management.

In accordance with our prior practice of compensating directors who were deemed to be "independent" under the AMEX rules relating to the independence of directors for their service on the Board, Audit Committee and Compensation Committee, following our 2007 annual meeting of stockholders on August 1, 2007, (i) each of our then-serving directors who was deemed to be "independent" under the AMEX rules relating to the independence of directors received a lump-sum annual cash retainer of $15,000 for his service on the Board, (ii) each then-serving member of the Audit Committee and each of our independent directors who then-served on the Compensation Committee received lump-sum annual cash retainers of $5,000 and $2,500, respectively, for his service on such committees, and (iii) each of our then-serving directors who was deemed to be "independent" under the AMEX rules relating to the independence of directors was awarded a grant of options to purchase 25,000 shares of our common stock under our 1999 Performance Equity Plan with an exercise price of $1.00 per share, which was the closing price of our common stock on the AMEX on August 1, 2007, and which fully vested immediately upon grant.

Following our 2008 annual meeting of stockholders on August 6, 2008, the Compensation Committee recommended, and the Board approved, changes to our practice of compensating directors who were deemed to be "independent" under the AMEX rules relating to the independence of directors for their service on the Board, Audit Committee and Compensation Committee. Accordingly, following our 2008 annual meeting of stockholders on August 6, 2008, (i) each of our then-serving directors who was deemed to be "independent" under the AMEX rules relating to the independence of directors received a lump-sum annual cash retainer of $20,000 for his service on the Board, (ii) each then-serving member of the Audit Committee and each of our independent directors who then served on the Compensation Committee received lump-sum annual cash retainers of $7,500 and $5,000, respectively, for his service on such committees, and (iii) each of our then-serving directors who was deemed to be "independent" under the AMEX rules relating to the independence of directors was awarded a grant of options to purchase 25,000 shares of our common stock under our 1999 Performance Equity Plan with an exercise price of $0.57 per share, which was the closing price of our common stock on the AMEX on August 6, 2008, and which fully vested immediately upon grant.

Upon his appointment on September 23, 2008, Laurent Le Portz was paid and granted compensation for his service on the Board, Audit Committee and Compensation Committee in accordance with our then current practices as described above. On October 10, 2008, the Compensation Committee recommended, and the Board approved, a change to our practice of compensating directors who were deemed to be "independent" under the AMEX rules relating to the independence of directors for their service on the Board, Audit Committee and Compensation Committee, such that the annual cash retainers described above would be paid in four equal quarterly installments instead of in one lump-sum. Upon their appointment on October 10, 2008, Jerry C. Benjamin was paid and granted compensation for his service on the Board and Audit Committee, and Lawrence G. Meyer was paid and granted compensation for his service on the Board, Audit Committee and Compensation Committee, in each case, in accordance with our then current practices as described above, including being paid annual cash retainers in four equal quarterly installments.

Historically, directors who were not deemed to be "independent" under the AMEX rules relating to the independence of directors, including directors who were employed by us, Teva Pharmaceutical Industries Limited or Teva North America, did not receive any compensation for their service on the Board, Audit Committee or Compensation Committee. On January 23, 2009, however, the Compensation Committee recommended, and the Board approved, an annual cash retainer of $20,000 to be paid in four equal quarterly installments to each of Patrice R. Debregeas and Paul F. Kennedy, neither of whom were at that time nor are currently employed by us, for their service on the Board, notwithstanding the fact that neither Mr. Debregeas nor Mr. Kennedy is an "independent" director under the AMEX rules relating to the independence of directors.

Director Compensation—2008

The following table sets forth certain information regarding the compensation paid to our directors for their service during the fiscal year ended December 31, 2008.

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards[5]	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Jerry C. Benjamin[1]	$ 6,875	—	$10,000	—	—		$16,875
Patrice R. Debregeas[2]	—	—	—	—	—	—	—
Mark W. Durand[3]	—	—	—	—	—	—	—
Richard S. Egosi[3]	—	—	—	—	—	—	—
Fernando L. Fernandez[4]	$32,500	—	$11,250	—	—		$43,750
Glenn L. Halpryn[4]	$32,500	—	$11,250	—	—		$43,750
John B. Harley, M.D., Ph.D.	$25,000	—	$11,250	—	—	$24,000[6]	$60,250
Paul F. Kennedy[2]	—	—	—	—	—	—	—
Itzhak Krinsky, Ph.D.[3]	—	—	—	—	—	—	—
Laurent Le Portz[2]	$13,125	—	$12,650	—	—		$25,575
Lawrence G. Meyer[1]	$ 8,125	—	$10,000	—	—		$18,125
Jose J. Valdes-Fauli[4]	$32,500	—	$11,250	—	—		$43,750

(1) Each of Messrs. Benjamin and Meyer was appointed to the Board on October 10, 2008.

(2) Each of Messrs. Debregeas, Kennedy and Le Portz was appointed to the Board on September 23, 2008.

(3) Each of Messrs. Durand and Egosi and Dr. Krinsky served on the Board until his resignation from the Board on September 2, 2008.

(4) Each of Messrs. Fernandez, Halpryn and Valdes-Fauli served on the Board until his resignation from the Board on October 10, 2008.

(5) Represents the dollar amount recognized for financial statement reporting purposes for the fiscal year ended December 31, 2008, in accordance with FAS 123(R), without taking into account an estimate of forfeitures related to service-based vesting, of stock option grants, including amounts from awards granted prior to 2008. Assumptions used in the calculation of these amounts are included in Note 12 to our Consolidated Financial Statements, *Shareholders' Equity*. There were no forfeitures during 2008. The table below sets forth, as of December 31, 2008, the aggregate number of stock options held by each of our directors who served on the Board during the fiscal year ended December 31, 2008 and who owned options to purchase shares of our common stock as of December 31, 2008:

Name	Stock Options
Jerry C. Benjamin	25,000
Fernando L. Fernandez	100,000
Glenn L. Halpryn	150,000
John B. Harley, M.D., Ph.D.	120,000
Laurent Le Portz	25,000
Lawrence G. Meyer	25,000
Jose J. Valdes-Fauli	135,000

(6) Represents the aggregate dollar amount earned by Dr. Harley during 2008 under that certain oral consulting agreement between Dr. Harley and ImmunoVision, pursuant to which Dr. Harley is paid $2,000 per month to provide ImmunoVision with technical guidance and business assistance on an as-needed basis.

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

Security Ownership of Certain Beneficial Owners and Management

The following table indicates, as of March 27, 2009, information about the beneficial ownership of our common stock by (1) each director as of March 27, 2009, (2) each Named Executive Officer (other than Charles R. Struby, Ph.D.), (3) all directors and executive officers as of March 27, 2009 as a group and (4) each person who we know beneficially owns more than 5% of our common stock. All such shares were owned directly with sole voting and investment power unless otherwise indicated.

Name	Shares (#)[1]	Percent of Class (%)
Patrice R. Debregeas[2][3] 79, rue de Miromesnil 75008, Paris, France	14,350,000	51.9%
Debregeas & Associes Pharma SAS[2][3] 79, rue de Miromesnil 75008, Paris, France	14,350,000	51.9%
Paul F. Kennedy[2][4] 81 Bd Suchet 75016, Paris, France	5,650,000	20.4%
Umbria LLC[2][4] c/o Fiduciaire Jean-Marc Faber 63-65, rue de Merl L, 2146, Luxembourg	2,850,000	10.3%
Giorgio D'Urso[5]	324,000[6]	1.2%
Kevin D. Clark	113,429[7]	*
Duane M. Steele	130,233[8]	*
Mark S. Deutsch	83,116[9]	*
Jerry C. Benjamin	25,000[10]	*
John B. Harley, M.D., Ph.D.	120,000[11]	*
Laurent Le Portz	25,000[12]	*
Lawrence G. Meyer	35,000[13]	*
All directors and executive officers as of March 27, 2009 as a group (10 persons)	20,631,778[14]	73.3%

* Represents beneficial ownership of less than 1%.

(1) For purposes of this table, beneficial ownership is computed pursuant to Rule 13d-3 under the Securities Exchange Act of 1934.

(2) Patrice R. Debregeas, Debregeas & Associes Pharma SAS, Paul F. Kennedy, and Umbria LLC, filed a Schedule 13D on September 12, 2008 as a "group," as such term is used in Section 13(d) of the Securities Exchange Act of 1934. Accordingly, each of Patrice R. Debregeas, Debregeas & Associes Pharma SAS, Paul F. Kennedy, and Umbria LLC, may be deemed to have an aggregate beneficial ownership of 20,000,000, or 72.3%, of the issued and outstanding shares of our common stock.

(3) Patrice R. Debregeas is the President and controlling person of Debregeas & Associes Pharma SAS, a company wholly-owned by Mr. Debregeas and members of his family.

(4) Paul F. Kennedy has shared voting and investment control of the shares of our common stock held by Umbria LLC, an entity wholly-owned by Mr. Kennedy and the sole director of which is Jean-Marc Faber.

(5) Mr. D'Urso resigned as our Chief Executive Officer and President and as a member of our Board of Directors, effective January 10, 2008, but his beneficial ownership of common stock is included in this table because he was a Named Executive Officer during 2008.

(6) Includes 9,000 shares of common stock owned by Mr. D'Urso's wife. Mr. D'Urso disclaims beneficial ownership of the shares of common stock owned by his wife.

(7) Includes options for 50,000 shares of common stock granted to Mr. Clark, and 42,529 shares of common stock owned by Mr. Clark through our 401(k) Plan.

(8) Includes options for 70,233 shares of common stock granted to Mr. Steele.

(9) Includes options for 65,116 shares of common stock granted to Mr. Deutsch.

(10) Includes options for 25,000 shares of common stock granted to Mr. Benjamin.

(11) Includes options for 120,000 shares of common stock granted to Dr. Harley.

(12) Includes options for 25,000 shares of common stock granted to Mr. Le Portz.

(13) Includes options for 25,000 shares of common stock granted to Mr. Meyer.

(14) Includes options for 100,000 shares of common stock granted to Dr. Struby, who was appointed our Chief Executive Officer and President on January 23, 2009, in connection with the employment agreement we entered into with him on March 27, 2009. Does not include the 324,000 shares of common stock beneficially owned by Mr. D'Urso and his wife as a result of Mr. D'Urso's resignation as our Chief Executive Officer and President and as a member of our Board of Directors, effective January 10, 2008.

Equity Compensation Plan Information

The following table sets forth information, as of December 31, 2008, with respect to compensation plans under which shares of our common stock are authorized for issuance.

Plan category	Number of shares to be issued upon exercise of outstanding stock options *(a)*	Weighted-average exercise price of outstanding stock options *(b)*	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) *(c)*
Equity compensation plans approved by stockholders	1,127,249	$2.53	1,473,939
Equity compensation plans not approved by stockholders	0	$—	0
Total	1,127,249	$2.53	1,473,939

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

Controlling Stockholder

Teva, indirectly through its wholly-owned IVAX subsidiary, owned approximately 72.3% of the outstanding shares of our common stock. On September 2, 2008, a group comprised of Debregeas & Associes Pharma SAS, a company wholly-owned by Patrice R. Debregeas and members of his family, Paul F. Kennedy and Umbria LLC, a company wholly-owned by Mr. Kennedy, purchased from Teva all of the approximately 72.3% of the outstanding shares of our common stock owned by Teva, indirectly through its wholly-owned IVAX, for an aggregate purchase price of $14,000,000, or $0.70 per share.

Certain Relationships and Related Transactions

In connection with the merger of the pre-merger IVAX Diagnostics, we entered into a shared services agreement with IVAX pursuant to which IVAX would continue to provide administrative and management services previously provided by IVAX to the pre-merger IVAX Diagnostics prior to the merger at IVAX' cost plus 15% for a period of three months. These services may include payroll, including printing paychecks and making associated tax filings; treasury, including cash management services such as disbursements, receipts, banking and investing; insurance, including procuring and administering policies; human resources, including administering employee benefits and plans; financial reporting, including public reports; income taxes; and information systems, including network and website hosting, phone and data systems, software licenses and information systems support. We no longer receive administrative and management services from IVAX.

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

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

Director Independence

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

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table sets forth the aggregate fees billed to us by PricewaterhouseCoopers LLP, our principal accountant for the fiscal years ended December 31, 2008 and 2007.

	For the years ended December 31,	
	2008	2007
Audit Fees	$336,000	$312,500
Audit-Related Fees	—	68,100
Tax Fees	—	—
All Other Fees	7,000	7,000
Total Fees	$343,000	$387,600

In the table above, pursuant to their definitions under the applicable regulations of the Securities and Exchange Commission, "audit fees" are fees for professional services rendered for the audit of our annual financial statements and review of our financial statements included in our quarterly reports on Form 10-Q and for services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements; "audit-related fees" are fees for assurance and related services that are reasonably related to the performance of the audit and review of our financial statements, and primarily include accounting consultations and audits in connection with potential acquisitions; "tax fees" are fees for tax compliance, tax advice and tax planning; and "all other fees" are fees for any services not included in the first three categories.

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

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

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

(1) FINANCIAL STATEMENTS

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

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2008 and 2007

Consolidated Statements of Operations for the years ended December 31, 2008 and 2007

Consolidated Statements of Shareholders' Equity for the years ended December 31, 2008 and 2007

Consolidated Statements of Cash Flows for the years ended December 31, 2008 and 2007

Notes to Consolidated Financial Statements

(2) FINANCIAL STATEMENT SCHEDULES

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

(3) EXHIBITS

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

Exhibit Number	Description	Method of Filing
3.1	Amended and Restated Certificate of Incorporation	Incorporated by reference to our Schedule 14A filed on June 25, 2002.
3.2	Amended and Restated Bylaws, as Amended	Incorporated by reference to our Form 10-K filed on March 31, 2008.
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*	Employment Agreement, dated as of March 27, 2009, by and between IVAX Diagnostics, Inc. and Charles Struby	Filed herewith.
10.4*	Employment Agreement, dated as of March 27, 2009 by and between IVAX Diagnostics, Inc. and Kevin Clark	Filed herewith.

Exhibit Number	Description	Method of Filing
10.5	1999 Performance Equity Plan	Incorporated by reference to our Form SB-2 filed on October 6, 1999.
10.6	1999 Stock Option Plan	Incorporated by reference to our Form 10-K filed on April 1, 2002.
10.7	Form of Nonqualified Stock Option Agreement (Employee)	Incorporated by reference to our Form 10-K filed on March 31, 2005.
10.8	Form of Nonqualified Stock Option Agreement (Non-Employee Director)	Incorporated by reference to our Form 10-K filed on March 31, 2005.
21.1	Subsidiaries of IVAX Diagnostics, Inc.	Filed herewith.
23.1	Consent of Independent Registered Public Accounting Firm—PricewaterhouseCoopers LLP	Filed herewith.
31.1	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith.
31.2	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith.
32.1	Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	**
32.2	Certification of Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	**

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

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

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, 2009

By: /s/ CHARLES R. STRUBY, PH.D.
Charles R. Struby, Ph.D.,
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.

Name	Capacity	Date
/s/ CHARLES R. STRUBY, PH.D. **Charles R. Struby, Ph.D.**	Chief Executive Officer and President (Principal Executive Officer)	March 30, 2009
/s/ MARK S. DEUTSCH **Mark S. Deutsch**	Chief Financial Officer and Vice President-Finance (Principal Financial Officer) (Principal Accounting Officer)	March 30, 2009
/s/ PATRICE R. DEBREGEAS **Patrice R. Debregeas**	Chairman of the Board of Directors	March 30, 2009
/s/ PAUL F. KENNEDY **Paul F. Kennedy**	Director	March 30, 2009
/s/ JERRY C. BENJAMIN **Jerry C. Benjamin**	Director	March 30, 2009
/s/ JOHN B. HARLEY, M.D., PH.D. **John B. Harley, M.D., Ph.D.**	Director	March 30, 2009
/s/ LAURENT LE PORTZ **Laurent Le Portz**	Director	March 30, 2009
/s/ LAWRENCE G. MEYER **Lawrence G. Meyer**	Director	March 30, 2009

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We have made forward-looking statements 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 the expectations, 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 strategic initiatives, including, without limitation, that we may not successfully implement some or all of our strategic initiatives and that our strategic initiatives may not make us a stronger, larger or more competitive company, allow us to develop, manufacture, and distribute worldwide, the reagents, test kits and diagnostic equipment that meet and/or exceed patients' and their physicians' needs for accurate and efficient in vitro diagnosis, improve our ability to compete and expand our reach in key countries around the world, result in profitability or improved manufacturing or marketing or make us a recognized presence in the healthcare industry; the risk that we may not successfully capitalize on being one of the few fully integrated in vitro diagnostics companies; the risk that we may not increase our operational efficiency in the manufacturing arena to the extent anticipated, or at all, and the risk that any such increase in operational efficiency may not result in our increased competitiveness; the risk that we may not increase the number and reach of our product offerings, whether through expanded internal capabilities or external distribution collaborations; the risk that we may not expand our current testing platform and/or disease target areas; the risks and uncertainties relating to the healthcare industry in general and our position within the healthcare industry, including, without limitation, the risk that the healthcare industry may not continue to grow at the rate we anticipate, or at all, the risk that our role in proper disease management may not increase with the continued aging of the global population, the risk that a shift to personalized medicine may not occur or, if it does so occur, the risk that we may not benefit from that shift, the risk that there may not be an increased demand for improved diagnostic capabilities or, if there is such an increase, that we may not be at the forefront of delivering leading edge diagnostic instrumentation and testing and the risk that we may not maintain or increase our market share or continue to build upon our customer list of well respected names in the healthcare industry; the risk that our recent change in majority ownership and subsequent change in management may not result in improved operations or strengthen our performance; the risks and uncertainties relating to our results of operations and financial condition, including, without limitation, the risk that our improved results may not continue in 2009 or any future period, the risk that our cash position may weaken, the risk that we may in the future incur short- or long-term debt, the risk that demand for and/or sales of our products may decrease, the risk that improvements in manufacturing and marketing may not result in profitability and the risk that we may not successfully contain our costs or otherwise increase our efficiencies and improve our margins; the risk that we may not successfully implement our two-year program to modernize and automate certain of our operations and the risk that, even if we successfully implement such program, it may not improve our competitive position or provide us with additional capacity to enable growth and expand our business; 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, 2008 which has been provided as a portion of this annual report. Many of these risks and factors are beyond our control.

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

www.ivaxdiagnostics.com