IVAX Diagnostics, Inc.

2009 Annual Report

IVAX
Diagnostics, Inc.

May 24, 2010

To Our Stockholders

2009 was the beginning of transformation for IVAX Diagnostics, which could best be described as a year committed to efforts designed to strengthen our performance in the future. I would specifically like to update you on the progress we made in the three areas of focus which I mentioned to you in last year's letter to stockholders.

The initial focus area for change was in our manufacturing arena within which we expect to significantly increase our operational efficiency and resulting competitiveness. I am pleased to report that the results of a recent audit conducted by the FDA of our Miami manufacturing facility provides a strong indication that we are currently in compliance with all FDA requirements for policies, procedures, processes, documentation, manufacturing, quality control, and supporting systems. Additionally, we are in the second year of our two-year program to modernize and automate certain operations in an effort to improve our competitive position. We continue to expect this program to provide us additional capacity to enable growth and expand our business.

A second focus area was to increase the number and reach of our product offerings, both through expanded internal capabilities and external distribution collaborations. In the fourth quarter of 2009, our European subsidiary, Delta, launched its CE-marked fully automated Enzyme Linked ImmunoSorbent Assay (ELISA) system for autoimmune and infectious disease testing, named the Mago®4. On October 1, 2009, we announced that one of our domestic subsidiaries, Diamedix, filed a 510(k) premarket submission with the FDA for its fully automated ELISA system for autoimmune and infectious disease testing, named the Mago®4S. Diamedix also recently signed a distribution agreement with Fumouze Diagnostics, a division of Sofibel S.A.S. of Paris, France, pursuant to which Fumouze Diagnostics will be the exclusive third party distributor of Diamedix and Delta's suite of diagnostic tests in France, as well as a distribution agreement with Nova Century Scientific, a subsidiary of IMMCO Diagnostics, Inc., pursuant to which Nova Century Scientific will market and sell in Canada 50 of Diamedix products, including analyzer instrumentation, under the Diamedix brand.

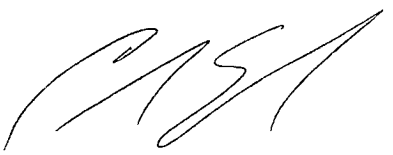
The third focus area was to expand our current testing platform and disease target areas. In July 2009, we announced our entry into an amended distribution agreement with IMMCO Diagnostics which provides Diamedix the right to distribute IMMCO Diagnostics' portfolio of products in the U.S. and which contains additional strategic initiatives related to the U.S. and Canadian markets under certain circumstances in the future. The products that will be distributed by Diamedix under the agreement with IMMCO Diagnostics include 60 autoimmune ELISA test kits, an increase from the 25 autoimmune ELISA test kits from IMMCO Diagnostics which were being distributed by Diamedix, and 150 Immunoflourescence Assay (IFA) test kits. Diamedix also recently entered into an agreement to distribute products developed by SCIMEDX Corporation on a global basis under the Diamedix brand, which expanded Diamedix' suite of products to include 26 additional ELISA test kits and 41 additional IFA test kits. In addition, we recently entered into a distribution agreement with Biomerica, Inc., pursuant to which Diamedix and Delta were granted the right to distribute Biomerica's products in the U.S. and globally, subject to certain country and product exclusions. The agreement with Biomerica includes distribution rights for 33 ELISA test kits in the areas of diabetes, gastrointestinal disease and bone/ mineral disorders, and more than 26 rapid point-of-care tests, which will be marketed under the Biomerica brand, or, if certain initial sales levels are achieved, under the Diamedix brand in the U.S. and the Delta brand internationally. We added over 300 assay test kits to our existing product lines through these distribution agreements, which we believe puts us in a better position to meet existing and potential customers' changing demands.

While our results for 2009 may demonstrate that transformation can present difficulties which we must overcome (net revenues for 2009 were $18,402,000, an 11.6% decrease compared with $20,819,000 in 2008, and net loss for 2009 was $4,458,000 compared to net income of $196,000 in 2008), we believe the initiatives that we undertook during 2009 and are continuing in 2010 will provide the groundwork for us to increase our sales and improve our performance in the months and years ahead.

Looking forward, we believe that 2010 will be a turnaround year for us. During January 2010, we reorganized our operations along functional lines in an effort to break down silos related to the conduct of our business through three separate subsidiaries. We believe that this reorganization will better position us to meet the goals we have set for 2010 and beyond. In addition, during January 2010, we appointed Steve Lufkin as General Manager. With a lifelong career in the healthcare industry, we expect that Steve's experience will strengthen the management team and improve efficiencies to help our company reach its full potential. Steve's initial focus will relate to our global sales and marketing operations, and regulatory activities. The addition of Steve to our management team has allowed Kevin Clark, our Chief Operating Officer, to focus primarily on our research and development, as well as our production and business development. We believe these areas of focus are central to our ability to successfully maximize our operating efficiencies and resulting cost competitiveness and to successfully identify and secure collaborations designed to further the future growth of our company.

We believe that our financial condition continues to be healthy. The health care industry is one of the few growth industries today. Our goal is to be a recognized presence in the health care industry while continuing to provide an important service to mankind – proper disease diagnosis. We believe the future for IVAX Diagnostics remains 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, 2009

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	**NYSE Amex**
(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 whether registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). 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, 2009, was approximately $5,178,000 computed by reference to the price at which the common equity was last sold on the NYSE Amex on such date.

As of March 26, 2010, 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, 2009

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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® 4, 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 Assay, or IFA, simultaneously. We have only marketed this updated version of the Mago® Plus outside of the United States. In the fourth quarter of 2009, we completed the development of, received all required regulatory approvals for, and began commercial deliveries of, an upgraded version of the Mago® Plus instrument, named the Mago® 4, which performs both ELISA and IFA techniques simultaneously, performs positive sample identification and utilizes 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. We are only marketing the Mago® 4 outside of the United States. We are developing a variation of the Mago® Plus, 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. We have sought, but have not yet received, all necessary regulatory approvals for the Mago® 4S. Accordingly, we currently expect to begin commercial deliveries of the Mago® 4S during the third quarter of 2010, provided we have received all required regulatory approvals by that time. 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 in 2007, 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 and Mago® 4S 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 European region (formerly called the Italian region)—contains our subsidiary located in Italy. For additional information about our two segments, see Note 11 to our Consolidated Financial Statements.

Delta, which IVAX Corporation, 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® 4, Mago® Plus and Aptus® systems, which include hardware, reagents, and software. Delta is currently developing the Mago® 4S. The Mago® 4, 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 and in international markets through third party distributors. Diamedix markets approximately 100 assays that the FDA has cleared. Approximately 50 of those assays are available to be run in conjunction with the Mago® Plus and Aptus® systems, while the remaining assays are run manually. We expect that all FDA approved assays presently marketed by Diamedix will be available to be run on the Mago® 4S upon our receipt of all regulatory approvals for, and the subsequent commercial launch of, this instrument system. 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 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. The Debregeas-Kennedy Group currently owns approximately 72.4% of the outstanding shares of our common stock.

Market. Our products are primarily associated with the in vitro diagnostics market. In vitro diagnostic assays are tests that are used to detect specific substances, usually either antigens or antibodies, outside the body. This usually involves using a blood sample or other bodily fluid sample for testing. The market for in vitro diagnostic products consists of reference laboratory and hospital laboratory testing, testing in physician offices, and over the counter testing, in which testing can be performed at home by the consumer. Industry analysts have estimated that the world market for in vitro diagnostics was $42.0 billion in 2007 and estimated to grow at a rate of 6% annually from 2008 to 2012. 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 autoimmune product line consists of approximately 20 ELISA test kits and 50 IFA assays 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. In addition, we obtained from two third party companies the rights to market and sell in Italy molecular biology multiarray tests for human papillomavirus and tuberculosis and a point of care lateral flow test for Celiac disease.

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® 4, 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® 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® 4 , Mago® Plus or Aptus® systems, we entered into an agreement with Dynex Technologies in 2008 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. We incurred $1.8 million in each of the years ended December 31, 2009 and 2008 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 and Mago® 4S 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, have been 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 menu of test kits 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 facility in Italy was delayed. Following a recently concluded inspection by the applicable notifying body required to obtain "CE Marking," we held a meeting with the applicable notifying body and were informed that our filing requires additional clinical data as a result of amended regulatory standards adopted by the applicable notifying body during the fourth quarter of 2009 that we must now comply with in order to receive approval. We believe that the product launch of our hepatitis test kits will be further delayed until the first quarter of 2011 due to the additional testing and documentation, and 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 European 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 diagnostics 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, 2009, we had approximately 105 full time employees, of whom 12 were managerial, 47 were technical and manufacturing, 10 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 the license, we would be required to take all steps reasonably necessary to change our name as soon as 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 are named the Mago® 4 and the Mago® 4S. During the fourth quarter of 2009, we began commercial deliveries of the Mago® 4, which we are only marketing outside of the United States. We are developing a variation of the Mago® Plus, named the Mago® 4S, which we intend to market in the United States. We have sought, but have not yet received, all necessary regulatory approvals for the Mago® 4S. 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® 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® 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® 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 as a result of the commercial release of the Mago® 4 or after the commercial release of the 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 and Mago® 4S 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 facility in Italy was delayed. Additionally, following a recently concluded inspection by the applicable notifying body required to obtain "CE Marking," we held a meeting with the applicable notifying body and were informed that our filing requires additional clinical data as a result of amended regulatory standards adopted by the applicable notifying body during the fourth quarter of 2009 that we must now comply with in order to receive approval. As a result, we believe that the product launch of our hepatitis test kits will be 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 and Mago® 4S as a platform for marketing our kits and to place 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, as described above, the timeframe during which we had expected to begin marketing

hepatitis test kits to be manufactured at our facility in Italy pursuant to a technology license was delayed due to the results of a recently concluded inspection by the applicable notifying body required to obtain "CE Marking" for the hepatitis test kits and a later meeting with the applicable notifying body where we were informed that our filing requires additional clinical data as a result of amended regulatory standards adopted by the applicable notifying body during the fourth quarter of 2009 that we must now comply with in order to receive approval. Based on the most recent delay in the anticipated product launch of our hepatitis test kits, 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 $0.4 million, reducing the value of our hepatitis technology product license to $0.3 million as of December 31, 2009, from $0.7 million as of December 31, 2008. At December 31, 2009, we had approximately $0.3 million of intangible assets and approximately $0.1 million of accrued payables relating to the hepatitis technology product license. This most recent delay, in addition to negatively impacting our ability to timely introduce our new hepatitis test kits, may also negatively impact our ability to 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 $0.3 million value of our product license of hepatitis technology and pay all or a portion of the accrued payables relating to the product license. Any of these factors could materially and adversely affect our business, prospects, operating results, financial condition or cash flows.

We have limited operating revenue and a history of primarily operational losses. If we continue to incur operating losses, then we may not have sufficient liquidity available to meet our needs.

For the year ended December 31, 2009, we recorded net revenues of $18.4 million and net loss of $4.5 million. For the year ended December 31, 2008, we recorded net revenues of $20.8 million and net income of $0.2 million. Our principal source of short-term liquidity is, and during the past three years has been, existing cash and cash equivalents and short-term marketable securities, which we believe will be sufficient to meet our operating needs and anticipated capital expenditures over the next twelve months. In connection with our evaluation of our operating results, financial condition and cash position, and specifically considering our results of operations and cash utilization during 2009, we have enacted, or are considering, various measures to improve future cash flow. To this end, we expect operating results to improve from the operating results achieved during 2009 based principally upon increases in revenue as a result of our anticipated commercial launch, after receiving all required regulatory approvals, of the Mago® 4S in the United States and increases in international instrumentation revenue. We also expect operating results to improve as a result of certain initiatives we have adopted or are considering in order to reduce expenses, as well as the anticipated expense reduction in 2010 as a result of the elimination of non-recurring professional fees which we incurred during 2009 in connection with our comprehensive review of our business plans and operations with the goal of improving our competitive position. Additionally, beginning in 2010, we expect to fund future placements in the United States of the DSX™ and DS2™ instrument systems from Dynex Technologies under reagent rental contracts by using a lease financing arrangement, rather than funding such instrument placements from our existing cash balances as we had done during 2009. We are also evaluating other various forms of financing arrangements. Any such financing arrangements would likely impose positive and negative covenants on us, which could restrict various aspects of our business, operations and finances. For the long-term, we intend to utilize principally existing cash and cash equivalents, as well as internally generated funds, which we anticipate will be derived primarily from our operations. Additionally, in the long-term, we expect to continue to explore the potential of selling our Miami facility and transferring the related production activities to a currently unidentified leased facility and using the cash proceeds from any such sale to fund our operating activities. There is, however, no assurance that existing cash and cash equivalents will, in the short- or long-term, 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 are insufficient to finance operations, if we are unable to operate on a profitable basis or internally generate funds from our operations, or if existing and possible future sources of liquidity described above are insufficient, then we may be required to issue debt or equity securities, incur indebtedness to finance our operations or curtail or reduce our operations.

There can be no assurance that, if we seek to raise additional funds through issuing debt or equity securities or incurring indebtedness, any such additional funds would be available on acceptable terms or at all.

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, 2009, our total inventories included approximately $0.3 million in Mago® 4S 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, the 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, 2009, our total inventories included approximately $0.3 million in Mago® 4S 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® 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 otherwise 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® 4, Mago® Plus and Aptus® instruments, and are currently developing and plan to manufacture the 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 2009, 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. Our international sales outside of Italy are through third party distributors. 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, including those included as part of the Annual Report on Form 10-K, 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 applicable accounting guidance. 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 a recently concluded inspection by the applicable notifying body required to obtain "CE Marking" for our hepatitis test kits, we held a meeting with the applicable notifying body and were informed that our filing requires additional clinical data as a result of amended regulatory standards adopted by the applicable notifying body during the fourth quarter of 2009 that we must now comply with in order to receive approval. As a result, we believe that the product launch of our hepatitis test kits will be further delayed. Accordingly, 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 $0.4 million, reducing the value of our hepatitis technology product license to $0.3 million as of December 31, 2009, from $0.7 million as of December 31, 2008. While we believe that we will be able to bring these hepatitis test 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 $0.3 million value of the hepatitis technology product license.

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 applicable accounting guidance, 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 or 2009. However, a continued decline in our market capitalization could require us to record additional impairment charges in future periods for the remaining goodwill at 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.

We may face significant uncertainty due to government healthcare reform.

Political, economic and regulatory influences are subjecting the healthcare industry to fundamental changes. We anticipate that the current administration, Congress and certain state legislatures will continue to review and assess the healthcare system and payment methods with an objective of ultimately reducing healthcare costs and expanding access. During March 2010, Congress approved, and the President signed into law, the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, which are expected to make significant changes to the healthcare industry. The uncertainties regarding the ultimate features of healthcare reform initiatives and their enactment and implementation, including with respect to the recently approved federal legislation, may have an adverse effect on our customers' purchasing decisions regarding our products. At this time, we cannot predict which, if any, additional healthcare reform proposals will be adopted, when they may be adopted or what impact they, or the recently approved federal legislation, may have on our business and operations, and any such impact may be adverse on our operating results and financial condition.

Cost containment measures 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 European 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. The cost of complying with these requirements is substantial and 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 may 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.

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, 2009 and 2008, our accounts receivable were $6.1 million and $6.1 million, respectively, and our allowance for doubtful accounts was $0.4 million and $0.4 million, respectively. As of December 31, 2009 and 2008, $4.2 million and $4.1 million, respectively, of our accounts receivable were due in Italy, and $0.2 million and $0.2 million, respectively, of our allowance for doubtful accounts related to Italian accounts receivable. As of December 31, 2009 and 2008, 48.1% and 50.9%, 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. There is no assurance that we will collect our outstanding accounts receivable or that our 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, 2009 and 2008, Delta represented 31.8% and 31.5%, respectively, of our net revenues. In addition, our current business plan includes a goal of expanding our product reach on a global basis and specifically in key regions in Europe and South America. 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, 2009 and 2008, 31.8% and 31.5%, respectively, of our net revenues were generated in currencies other than the United States dollar, and we anticipate that this percentage may increase in future periods as a result of our efforts to expand our product reach internationally. 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. The evaluation of acquisition opportunities may divert management's attention from our operations, and 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 NYSE Amex.

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. We engaged a third party firm to assist us with this process. Because we are not a large accelerated filer or an 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. Pursuant to the current rules and regulations of the Securities and Exchange Commission, in our Annual Report on Form 10-K for the year ending December 31, 2010 and for each fiscal year thereafter, our management will continue to 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 are held at a single brokerage firm.

Substantially all of our cash and cash equivalents 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 72.4% of the issued and outstanding shares of our common stock. Mr. Debregeas, individually, may be deemed to beneficially own approximately 51.0% 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 Mr. Debregeas, acting individually, and, in each case, 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. Messrs. Debregeas and Kennedy both currently serve on our Board of Directors, and Mr. Debregeas currently serves as our Chairman of the Board of Directors.

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

In 2001, we entered into a use of name license agreement with IVAX whereby IVAX granted us a non-exclusive, royalty free license to use the name "IVAX." IVAX may terminate this license at any time upon

90 days' written notice. There can be no assurance that IVAX will not terminate this license agreement. Upon termination of the license agreement, we would be 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 NYSE Amex (formerly known as the American Stock Exchange) since March 15, 2001. Because the Debregeas-Kennedy Group collectively owns approximately 72.4% 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 those 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,
- healthcare regulatory reform, 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 our 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, the success of our upgraded version of the Mago® Plus instrument, named the Mago® 4, and our development and future commercial release of the Mago® 4S;

- our ability to receive regulatory approval for the Mago® 4S when expected, or at all;
- the ability of the 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® 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® 4S or as a result of future demand for the 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 as a result of the commercial release of the Mago® 4 or after the commercial release of the 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;
- the success of our recently completed comprehensive review of our business plans and operations and the initiatives that we have implemented or may in the future implement based on the results of such review;
- our ability to improve our competitive position to the extent anticipated, or at all, as a result of our recently completed comprehensive review or our business plans and operations and the initiatives that we have implemented or may in the future implement based on the results of such review;
- the impact on our financial condition, operating results and cash flows of the expenses which we may incur as a result of the initiatives that we have implemented or may in the future implement based on the results of our recently completed comprehensive review of our business plans and operations, including the risk that our expenses relating to such initiatives may not decrease in future periods from the level of expenses incurred during 2009 in connection with the review, and the risk that such expenses may continue for longer than anticipated;
- our ability to generate positive cash flow or otherwise improve our liquidity, whether from existing operations, strategic initiatives or possible future sources of liquidity, including, without limitation, from issuing debt or equity securities, incurring indebtedness or curtailing or reducing our operations;
- 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, including, without limitation, our ability to increase our presence in key countries in Europe and South America as well as other international markets, or become a leader in the diagnostics industry;
- the impact the existing global economic conditions may have on our financial condition, operating results and cash flows;
- the impact of healthcare regulatory reform;
- 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;
- the limitation on our ability to utilize our net operating losses and its impact on our financial condition and operating results;
- 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, and thereafter introduce and market, our own hepatitis products in the European Union when expected, or at all, including the potential that any further delays may require us to record an additional impairment charge with respect to the value of our hepatitis technology product license or pay all or a portion of our accrued payables relating to the product license;
- 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;
- the impact that the recent delay in the anticipated product launch of our own hepatitis products may have on our ability to achieve our originally anticipated sales levels of these products;
- 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 or lease 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 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, individually, or together with 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. (REMOVED AND RESERVED)

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 NYSE Amex (formerly known as the American Stock Exchange) and trades under the symbol "IVD."

As of the close of business on March 26, 2010, there were approximately 46 holders of record of our common stock.

The following table sets forth the high and low sales prices of a share of our common stock for each quarter in 2009 and 2008, as reported by the NYSE Amex (formerly known as the American Stock Exchange):

2009	High	Low
Fourth Quarter	$0.74	$0.41
Third Quarter	0.84	0.52
Second Quarter	0.72	0.30
First Quarter	0.73	0.28

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

We did not declare or pay cash dividends on our common stock during 2009 or 2008, and we do not intend to pay any cash dividends in the foreseeable future.

ITEM 6. SELECTED FINANCIAL DATA

Not required.

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

The following discussion and analysis should be read in conjunction with our Consolidated Financial Statements and the related Notes to Consolidated Financial Statements on pages 40 to 65 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 European region (formerly called 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 100 assays that the FDA has cleared. Approximately 50 of those assays are available to be run in conjunction with the Mago® Plus and Aptus® systems, while the remaining assays are run manually.

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® 4, Mago® Plus and Aptus® systems, which include hardware, reagents, and software. The Mago® 4, 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. The Debregeas-Kennedy Group currently owns approximately 72.4% of the outstanding shares of our common stock.

RESULTS OF OPERATIONS

YEAR ENDED DECEMBER 31, 2009 COMPARED TO THE YEAR ENDED DECEMBER 31, 2008

OVERVIEW

Net loss totaled $4,458,000 in 2009 compared to net income of $196,000 in 2008. Operating loss was $4,350,000 in 2009 compared to operating income of $243,000 in 2008. Net loss and loss from operations in 2009 resulted primarily from declines in revenues and gross profit, and from higher general and administrative and selling expenses. Net revenues decreased $2,417,000 to $18,402,000 in 2009 from $20,819,000 in 2008, consisting of a decrease in domestic net revenues of $1,717,000 and a decrease in net revenues from European operations of $700,000, including the effect of currency fluctuations of the United States dollar relative to the Euro. Gross profit decreased $2,329,000 to $10,102,000 in 2009 from $12,431,000 in 2008, primarily as the result of the decline in net revenues, including the effect of exchange rate fluctuations. Gross profit as a percentage of revenues decreased to 54.9% during 2009 from 59.7% during 2008, principally as a result of sales price declines from European operations, an increase in domestic manufacturing costs, reduced production volume and unfavorable manufacturing variances. Operating expenses increased to $14,452,000 in 2009 from $12,674,000 in 2008 primarily as a result of a $1,311,000 increase in general and administrative expenses, principally due to costs we incurred in connection with our recently completed comprehensive review of our business plans and operations, which we initiated during 2009 with the goal of improving our competitive position. Selling expenses increased $651,000 to $5,584,000 in 2009 from $4,933,000 in 2008 principally due to an increase in domestic selling expenses of $520,000, while research and development expenses declined by $24,000. Additionally, non-cash charges recorded during 2009 decreased by $160,000 compared to 2008, as we recorded a $400,000 impairment with respect to the value of our hepatitis technology product license during 2009 compared to a $560,000 impairment with respect to the value of such technology license during 2008. Total other income decreased by $489,000 in 2009 compared to 2008, with reductions in interest income and foreign currency gains. No significant fluctuations occurred in our income tax provision during 2009 compared to 2008.

NET REVENUES AND GROSS PROFIT

	2009	2008	Period over Period (Decrease)
Net Revenues			
Domestic	$12,545,000	$14,262,000	$(1,717,000)
European	5,857,000	6,557,000	(700,000)
Total	18,402,000	20,819,000	(2,417,000)
Cost of Sales	8,300,000	8,388,000	(88,000)
Gross Profit	$10,102,000	$12,431,000	$(2,329,000)
% of Total Net Revenues	54.9%	59.7%	

Net revenues in 2009 decreased $2,417,000, or 11.6%, from 2008. This decrease was comprised of decreases of $1,717,000 in net revenues from domestic operations and $700,000 in net revenues from European operations. Contributing to the decline in net revenues is the effect of a decrease of $365,000 in European revenues due to fluctuation of the United States dollar relative to the Euro, as further discussed in "Currency Fluctuations" below. Additionally, it is our belief that the existing global economic conditions contributed to the decline in net revenues for both the domestic and European segments. As measured in Euros, revenues from European operations decreased 5.1% compared to 2008. The decrease in revenues from European operations was principally due to sales price declines for our sales within Italy, which were partially offset by volume increases in allergy product sales to our international distributors. Domestic net revenues in 2009 decreased 12.0% compared to 2008. The decrease in domestic revenue was primarily due to declines in reagent sales to instrumentation customers, as well as a decrease in contract manufacturing revenue.

Gross profit in 2009 decreased $2,329,000, or 18.7%, from the prior year. The decrease in gross profit was primarily attributable to the decline in net revenues, including the effect of exchange rate fluctuations described above. The sales price declines from European operations discussed above also contributed to the decrease in gross profit as a percentage of net revenues to 54.9% in 2009 from 59.7% in 2008 as did an increase in domestic manufacturing costs, reduced production volume and unfavorable manufacturing variances.

OPERATING EXPENSES

	2009	% of Revenue	2008	% of Revenue	Period over Period Increase (Decrease)
Selling Expenses					
Domestic	$ 3,631,000	19.7%	$ 3,111,000	14.9%	$ 520,000
European	1,953,000	10.6%	1,822,000	8.8%	131,000
Total	5,584,000	30.3%	4,933,000	23.7%	651,000
General and Administrative	6,675,000	36.3%	5,364,000	25.8%	1,311,000
Research and Development	1,793,000	9.7%	1,817,000	8.7%	(24,000)
Impairment of Product License	400,000	2.2%	560,000	2.7%	(160,000)
Total Operating Expenses	$14,452,000	78.5%	12,674,000	60.9%	$1,778,000

The most significant variations in operating expenses occurred in general and administrative and selling expenses. General and administrative expenses increased $1,311,000 in 2009 compared to 2008 primarily due to increased professional fees, as well as higher travel and severance expenses, incurred in connection with our recently completed comprehensive review of our business plans and operations initiated during 2009 with the goal of improving our competitive position. In addition, general and administrative expenses increased during 2009 due to significant bad debt recoveries recorded in Italy in 2008 that reduced general and administrative expenses in that year. Partially offsetting these increases were declines in compensation costs and legal fees during 2009 due to legal fees which were incurred in 2008 primarily relating to the acquisition by the Debregeas-Kennedy Group of the 72.3% of our common stock previously owned by Teva. Selling expenses increased $651,000 in 2009 compared to 2008. Selling expenses amounted to 30.3% of net revenues in 2009 compared to 23.7% of net revenues in 2008. The increase in domestic selling expenses of $520,000 was partially the result of costs associated with increased professional fees incurred in connection with our recently completed comprehensive review of our business plans and operations initiated during 2009 with the goal of improving our competitive position. Additionally, domestic selling expenses increased as a result of an increase in personnel, as we filled open sales positions in domestic territories, as well as increased travel costs. The increase of $131,000 in European selling expenses was principally due to an increase in labor costs, partially due to the reallocation of personnel described below.

Research and development expenses decreased $24,000 in 2009 compared to 2008. Domestic research and development expenses, which increased by $74,000 from 2008, included costs associated with our September 30,

2009 510(k) premarket submission filing with the FDA for our next-generation fully automated ELISA system for autoimmunue and infectious disease testing, named the Mago® 4S. We anticipate that the Mago® 4 and Mago® 4S will be our primary platforms for marketing our kits. Domestic research and development expenses also included costs associated with the validation of our test kits on the DSX™ and DS2™ instrument systems that we began to promote in conjunction with our test kits. European research and development expenses decreased by $98,000 compared to 2008, primarily due to a decrease in hepatitis product development costs as personnel were allocated to other departments while we await authorization for "CE Marking" in the European Union partially offset by an increase in instrumentation development costs related to the Mago® 4 and Mago® 4S. 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.

During 2009 and 2008, we recorded non-cash impairment charges of $400,000 and $560,000, respectively, relating to the value of our product license of hepatitis technology. Based principally upon the progress we have made during 2009 to meet the requirements specified in July 2009 by the applicable notifying body to obtain "CE Marking" and amended regulatory standards adopted by the applicable notifying body during the fourth quarter of 2009 that we must now comply with in order to receive approval, we revised our 2009 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. Additionally, principally as a result of a 2008 inspection by the applicable notifying body required for us to obtain "CE Marking," we revised our 2008 assumptions supporting the computation of the fair value of the license to reflect the delay in product launch and the possibility of a decrease in projected market share as a result of the delay. Based upon this methodology, and considering the impact of global economic conditions, we recorded these non-cash product license impairment charges to operations in 2009 and 2008.

LOSS FROM OPERATIONS

Loss from operations totaled $4,350,000 in 2009 compared to a loss from operations of $243,000 in 2008. Loss from operations in 2009 was composed of a $3,032,000 loss from domestic operations, including the $400,000 charge for the impairment of our product license of hepatitis technology, and a loss from European operations of $1,337,000. 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 European operations of $174,000. Domestic operations include corporate expenditures, including costs required to maintain our status as a public company.

OTHER INCOME, NET

Interest income decreased $273,000 to $19,000 in 2009 from $292,000 in 2008 due principally to significantly lower average yields, on lower average cash balances invested, that are available in the current economic environment on select money market instruments in which we have invested in accordance with our investment policy. Additionally, our interest income in 2008 included the benefit of above market penalty rates received by us as a result of our prior investments in auction rate securities which had experienced failed auctions, and interest we received in conjunction with our receipt of a tax payment from the Italian government. Other income, net totaled $37,000 during 2009, compared to other income, net of $253,000 in 2008. Amounts included in other income, net in 2009 and 2008 were primarily net foreign currency gains or losses on transactions, particularly by our European subsidiary, which were denominated in currencies other than the subsidiary's functional currency. Also included in other income, net during 2008 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. 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 income tax provisions of $164,000 during 2009 and $106,000 during 2008. Included in the foreign current income tax provision for 2009 was $21,000 resulting from an assessment related to the settlement of Italian tax audit issues for the 2005 tax year. The remaining current portion of our tax provisions in both 2009 and 2008 relates to Italian local income taxes based upon applicable statutory rates effective in Italy, while the deferred tax provision in these same periods relates to domestic tax deductible goodwill. No current domestic tax benefit was recorded during 2009 despite our domestic losses because we had a full valuation allowance against the domestic net deferred income tax assets. No current domestic tax provision was recorded during 2008 due to the expected utilization of prior period net operating losses to offset current domestic taxable income.

NET INCOME (LOSS)

We generated a net loss of $4,458,000 in 2009 compared to net income of $196,000 in 2008. Our basic and diluted net loss per common share was $0.16 in 2009 compared to basic and diluted income per common share of $0.01 in 2008. The net loss in 2009 and net income in 2008 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, 2009, our working capital was $10,993,000 compared to $15,304,000 at December 31, 2008. Cash and cash equivalents totaled $4,199,000 at December 31, 2009 and $4,421,000 at December 31, 2008. Short-term marketable securities were $0 at December 31, 2009 and $4,100,000 at December 31, 2008.

Net cash flows of $3,234,000 were used in operating activities during 2009 compared to $648,000 that were used in operating activities during 2008. Cash used in operating activities during 2009 was primarily the result of the net loss of $4,458,000 partially offset by non-cash items of $1,180,000 and changes in operating assets and liabilities of $43,000. The non-cash items include depreciation and amortization, the product license impairment charge, non-cash compensation, a net recovery of doubtful accounts receivable and deferred income taxes. Cash provided by changes in operating assets and liabilities was primarily due to $151,000 provided as a result of a decrease in accounts receivable and $111,000 as a result of increases in other long-term liabilities. Partially offsetting this amount was cash of $254,000 used as a result of increases in inventory. 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 which had 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 European subsidiary. 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.

Net cash of $3,023,000 was provided by investing activities during 2009 compared to $1,333,000 that was provided by investing activities during 2008. The increase in cash provided by investing activities in 2009 was primarily the result of our sale to UBS of all of the auction rate securities in which we invested at their par value of $4,100,000 as a result of our exercise of rights we received from UBS as discussed below. Cash utilized for the acquisitions of equipment on lease and capital expenditures partially offset this increase in investing activities. Cash flows provided by investing activities during 2008 were primarily the result of net sales of $1,925,000 of auction rate securities in which we had invested, partially offset by capital expenditures and acquisitions of equipment on lease in 2008.

There were no financing activities during 2009 or 2008. We did not repurchase any of our common stock during 2009 or 2008, whether as part of the common stock repurchase program approved by our Board of Directors in May 2002 or otherwise.

Substantially all of our cash and cash equivalents 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.

During the year ended December 31, 2008, 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 had historically provided a liquid market for auction rate securities, as this mechanism generally allowed 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 were unable to liquidate their securities.

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 did not own, or invest 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. Beginning 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 failed auctions. As a result of these failed auctions, we were unable to 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 Securities and Exchange Commission, the New York Attorney General, the Massachusetts Securities Division 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 of 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 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.

Our product research and development expenditures are expected to be approximately $1,700,000 during 2010. Actual expenditures will depend upon, among other things, the outcome of clinical testing of products under development, delays or changes in government required testing and approval procedures, technological and competitive developments, strategic marketing decisions and liquidity. There can be no assurance that these expenditures will result in the development of new products or product enhancements, that we will successfully complete products under development, that we will obtain regulatory approval or that any approved product will be produced in commercial quantities, at reasonable costs, and be successfully marketed. In addition, we estimate that cash of approximately $500,000 will be required in 2010 to improve and expand our facilities, equipment and information systems. This estimate does not include, however, expenditures relating to our plans to continue

our search to relocate to a new location for our corporate headquarters and the operations of Diamedix, one of our domestic subsidiaries. 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, 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 European subsidiary, Delta Biologicals, in maintaining its compliance with capital requirements established by Italian law. In connection with our evaluation of our operating results, financial condition and cash position, and specifically considering our results of operations and cash utilization during 2009, we have enacted, or are considering, various measures to improve future cash flow. To this end, we expect operating results to improve from the operating results achieved during 2009 based principally upon increases in revenue as a result of our anticipated commercial launch, after receiving all required regulatory approvals, of the Mago® 4S in the United States and increases in international instrumentation revenue. We also expect operating results to improve as a result of certain initiatives we have adopted or are considering in order to reduce expenses, as well as the anticipated expense reduction in 2010 as a result of the elimination of non-recurring professional fees incurred during 2009 in connection with our comprehensive review of our business plans and operations with the goal of improving our competitive position. Additionally, beginning in 2010, we expect to fund future placements in the United States of the DSX™ and DS2™ instrument systems from Dynex Technologies under reagent rental contracts by using a lease financing arrangement, rather than funding such instrument placements from our existing cash balances as we had done during 2009. We are also evaluating other various forms of financing arrangements. Any such financing arrangements would likely impose positive and negative covenants on us, which could restrict various aspects of our business, operations and finances. For the long-term, we intend to utilize principally existing cash and cash equivalents, 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. Additionally, in the long-term, we expect to continue to explore the potential of selling our Miami facility and transferring the related production activities to a currently unidentified leased facility and using the cash proceeds from any such sale to fund our operating activities. If we are not successful in improving our operating results and cash flows or if existing and possible future sources of liquidity described above are insufficient, then 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 we make the determination to increase the allowance for doubtful accounts.

Off-Balance Sheet Arrangements. As of December 31, 2009, 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, 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 include a Mago® Plus instrument or a DSX™ or DS2™ instrument system, which in either case typically remains our property. We also include any required instrument service. Both the instrumentation and service 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 European 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 we make the determination to increase the allowance for doubtful accounts. Our allowances for doubtful accounts were $356,000 at December 31, 2009 and $358,000 at December 31, 2008. We recorded net recoveries of accounts receivable of $5,500 in 2009 and $633,000 in 2008.

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 $499,000 and $460,000 as of December 31, 2009 and 2008, respectively. Included in our inventory balance at December 31, 2009 was approximately $260,000 in Mago® 4S instrumentation and instrument components in anticipation of our pending commercial product launch. On September 30, 2009, we filed a 510(k) premarket submission with the FDA for the Mago® 4S. We received feedback from the FDA requesting that we provide additional analytics and clinical test data, and we are working with the FDA to provide the requested information and expedite the approval process. Commercial deliveries of the Mago® 4S will await our receipt of such regulatory approval, after which we expect to begin commercial deliveries in the third quarter of 2010. We also had approximately $200,000 of raw material inventory relating to our hepatitis product included in our inventory balance at December 31, 2009, substantially all of which has shelf life exceeding five years. Our hepatitis product is currently pending regulatory approval.

GOODWILL AND OTHER INTANGIBLES

Pursuant to accounting guidance, 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, 2009 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 2009. 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.

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 $870,000 of goodwill recorded at 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. We made the first three milestone payments upon the achievement of the enumerated performance objectives in prior years, while the fourth and final milestone payment will not be due until after we receive "CE Marking" approval from the European Union for our hepatitis products.

During the fourth quarter of 2009, 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 $400,000, reducing the carrying value of the product license to $283,000 as of December 31, 2009, from $683,000 as of December 31, 2008. 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. Based upon the progress we have made during 2009 to meet the requirements specified in July 2009 by the applicable notifying body to obtain "CE Marking" and amended regulatory standards adopted by the applicable notifying body during the fourth quarter of 2009 that we must now comply with in order to receive approval, 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 six years and revenue and gross margin estimates beginning in 2011, a range of potential outcomes was determined and weighted based upon an estimated probability of occurrence. Estimated future cash flows generated by the technology granted by the product license was then calculated using a discount rate of 30%, 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 $283,000 intangible product license of hepatitis technology asset.

During the fourth quarter of 2008, following the results of an inspection by the applicable notifying body required to obtain "CE Marking," 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 value of the product license to $682,936 as of December 31, 2008, from $1,242,936 as of December 31, 2007. The methodology and assumptions utilized to compute the 2008 non-cash impairment charge were similar to the methodology and assumptions described above to compute the non-cash impairment charge recorded in the fourth quarter of 2009, however, with respect to the 2008 fair value determination, we utilized a discount rate of 20% and a forecasted seven year cash flow period.

STOCK-BASED COMPENSATION

Stock-based compensation expense for all stock-based compensation awards is based on the grant-date fair value estimate calculated in accordance with applicable accounting guidance. 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 experienced net domestic losses from operations. In accordance with GAAP, we are required to 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 both our domestic and foreign operations, we have provided a full valuation allowance against our deferred tax assets. 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 ability to use 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 the outstanding shares of our common stock previously owned by Teva, indirectly through its wholly-owned IVAX subsidiary. As a result of that acquisition, our ability to utilize net operating loss carryforwards to offset future taxable income is currently limited to approximately $900,000 per year, plus both any limitation unused since the acquisition and any unused net operating losses generated after the September 2, 2008 acquisition date. The amount of the annual limitation will be adjusted upwards for any recognized built-in gains on certain assets sold during the five year period commencing with the ownership change. Our results for the year ended December 31, 2009 were not impacted by these limitations.

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 January 2010, the Financial Accounting Standards Board, or FASB, issued authoritative guidance intended to improve disclosure about fair value measurements. The guidance requires entities to disclose significant transfers in and out of fair value hierarchy levels and the reasons for the transfers and to present information about purchases, sales, issuances, and settlements separately in the reconciliation of fair value measurements using significant unobservable inputs (Level 3). Additionally, the guidance clarifies that a reporting entity should provide fair value measurements for each class of assets and liabilities and disclose the inputs and valuation techniques used for fair value measurements using significant other observable inputs (Level 2) and significant unobservable inputs (Level 3). This guidance is effective for interim and annual periods beginning after December 15, 2009 except for the disclosure about purchases, sales, issuances and settlements in the Level 3 reconciliation, which will be effective for interim and annual periods beginning after December 15, 2010. As this guidance provides only disclosure requirements, the adoption of this standard will not impact our consolidated financial statements.

In October 2009, the FASB issued amended revenue recognition authoritative guidance for arrangements with multiple deliverables. The new authoritative guidance eliminates the residual method of revenue recognition and allows the use of management's best estimate of selling price for individual elements of an arrangement when vendor specific objective evidence ("VSOE"), vendor objective evidence ("VOE") or third-party evidence ("TPE") is unavailable. This guidance is effective for all new or materially modified arrangements entered into on or after January 1, 2011, with earlier application permitted as of the beginning of any prior fiscal year. Full retrospective application of the new guidance is optional. We are currently assessing the impact that the implementation of this new guidance will have on our financial position and operations.

In October 2009, the FASB issued authoritative guidance which amends the scope of existing software revenue recognition accounting. Tangible products containing software components and non-software

components that function together to deliver the product's essential functionality would be scoped out of the accounting guidance on software and accounted for based on other appropriate revenue recognition guidance. This guidance is effective for all new or materially modified arrangements entered into on or after January 1, 2011, with earlier application permitted as of the beginning of any prior fiscal year. Full retrospective application of the new guidance is optional. This guidance must be adopted in the same period that we adopt the amended accounting for arrangements with multiple deliverables described in the preceding paragraph. We are currently assessing the impact that the implementation of this new guidance will have on our financial position and operations.

On July 1, 2009, the FASB issued the FASB Accounting Standards Codification, or the Codification. The Codification became the single authoritative source of GAAP recognized by the FASB. The Codification superseded all previously-existing non-Securities and Exchange Commission accounting and reporting standards, and all other non-grandfathered non-Securities and Exchange Commission accounting literature not included in the Codification became nonauthoritative. The Codification was effective for interim and annual reporting periods ending after September 15, 2009. We adopted the Codification for the quarter ended September 30, 2009. Our adoption of the Codification did not have any impact on our financial position and operations as this change is disclosure-only in nature.

In June 2009, the FASB issued authoritative guidance which amends the consolidation guidance applicable to variable interest entities and requires enhanced disclosures intended to provide users of financial statements with more transparent information about an enterprise's involvement in a variable interest entity. This guidance will be effective beginning with our consolidated financial statements for the year ending December 31, 2010 and the quarterly periods thereof. We do not expect the impact of adoption to be material on our financial position and operations.

In June 2009, the FASB issued authoritative guidance which eliminates the concept of a qualifying special-purpose entity, changes the requirements for derecognizing financial assets and requires enhanced disclosure to provide financial statement users with greater transparency about transfers of financial assets, including securitization transactions and an entity's continuing involvement in and exposure to the risks related to the transfer of financial assets. This guidance will be effective beginning with our consolidated financial statements for the year ending December 31, 2010 and the quarterly periods thereof. We do not expect the impact of adoption to be material on our financial position and operations.

In May 2009, the FASB issued amended authoritative guidance on subsequent event accounting which sets forth: (i) the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements; (ii) the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements; and (iii) the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. These guidelines were effective for interim and annual periods ending after June 15, 2009, and we adopted them in the quarter ended June 30, 2009. The adoption of this guidance did not have a material impact on our financial position and operations.

In April 2009, the FASB issued authoritative guidance on determining fair value when the volume and level of activity for an asset or liability has significantly decreased, and in identifying transactions that are not orderly. Based on the guidance, if an entity determines that the level of activity for an asset or liability has significantly decreased and that a transaction is not orderly, further analysis of transactions or quoted prices is needed, and a significant adjustment to the transaction or quoted prices may be necessary to estimate fair value. The guidance was effective on a prospective basis for interim and annual periods ending after June 15, 2009. We adopted this guidance in the quarter ended June 30, 2009. The adoption of this guidance did not have a material impact on our financial position and operations.

In April 2009, the FASB issued authoritative guidance regarding interim disclosures about the fair value of financial instruments which were previously only disclosed on an annual basis. Entities are now required to

disclose the fair value of financial instruments which are not recorded at fair value in the financial statements in both their interim and annual financial statements. The new requirements were effective for interim and annual periods ending after June 15, 2009 on a prospective basis. We adopted these requirements in the quarter ended June 30, 2009. The adoption of these requirements did not impact our financial position and operations, as the requirements relate only to additional disclosures.

In April 2008, the FASB issued new authoritative guidance regarding the determination of the useful lives of intangible assets. In developing assumptions about renewal or extension options used to determine the useful life of an intangible asset, an entity needs to consider its own historical experience adjusted for entity-specific factors. In the absence of that experience, an entity shall consider the assumptions that market participants would use about renewal or extension options. The new requirements apply to intangible assets acquired after January 1, 2009. The adoption of these new rules did not have a material impact on our financial position and operations.

In March 2008, the FASB issued new authoritative disclosure requirements regarding derivative instruments and hedging activities. Entities must now provide enhanced disclosures on an interim and annual basis regarding how and why the entity uses derivatives, how derivatives and related hedged items are accounted for, and how derivatives and related hedged items affect the entity's financial position, financial results and cash flows. We adopted these new requirements on January 1, 2009. The adoption of these new requirements did not impact our financial position and operations, as they were disclosure-only in nature.

In December 2007, the FASB issued new authoritative guidance on noncontrolling interests in consolidated financial statements. This guidance requires that the noncontrolling interest in the equity of a subsidiary be accounted for and reported as equity, provides revised guidance on the treatment of net income and losses attributable to the noncontrolling interest and changes in ownership interests in a subsidiary and requires additional disclosures that identify and distinguish between the interests of the controlling and noncontrolling owners. We adopted this new guidance on January 1, 2009. The adoption of this guidance did not have a material impact on our financial position and operations.

In December 2007, the FASB issued revised authoritative guidance regarding business combinations. The guidance significantly changed 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 the guidance, 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. The guidance 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 was not permitted. The effect of this guidance on our financial position and operations will be dependent on the nature and terms of any future business combinations that we consummate.

CURRENCY FLUCTUATIONS

For the years ended December 31, 2009 and 2008, approximately 31.8% and 31.5%, respectively, of our net revenues were generated in currencies other than the United States dollar. We expect that this percentage may increase in the future as a result of our efforts to increase our international presence, particularly in key markets in Europe and South America. 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 decreases of approximately $365,000 in net revenues in 2009 compared to 2008. During the years ended December 31, 2009 and 2008, 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 2009, our subsidiary in Italy generated 31.8% 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 income tax provisions of $164,000 for the year ended December, 31, 2009 compared to $106,000 for the year ended December 31, 2008. Our income tax provisions for the years ended December 31, 2009 and 2008 were 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 2009 due to losses incurred during the year, or 2008 due to the expected utilization of prior period net operating losses to offset current domestic taxable income. Included in the 2009 foreign current income tax provision was $21,000 resulting from an assessment related to the settlement of Italian tax audit issues for the 2005 tax year. The remaining foreign current income tax provision during 2009 and 2008 was a result of Italian local income taxes based upon applicable statutory rates effective in Italy.

As of December 31, 2009, we had no net domestic or foreign deferred tax asset, as a full valuation allowance has been established against deferred tax assets. As of December 31, 2009, we had net deferred tax liabilities of $302,000 relating to tax deductible goodwill at ImmunoVision, and we recorded a corresponding deferred tax provision of $63,000 in 2009. 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. As a result of that acquisition, our ability to utilize net operating loss carryforwards to offset future taxable income is currently limited to approximately $900,000 per year, plus both any limitation unused since the acquisition and any unused net operating losses generated after the September 2, 2008 acquisition date. The amount of the annual limitation will be adjusted upwards for any recognized built-in gains on certain assets sold during the five year period commencing with the ownership change. Our results for the year ended December 31, 2009 were not impacted by these limitations.

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. and its subsidiaries (the "Company") at December 31, 2009 and 2008, and the results of their operations and their cash flows for each of the two years in the period ended December, 31, 2009 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

PricewaterhouseCoopers LLP
Philadelphia, Pennsylvania
March 31, 2010

IVAX Diagnostics, Inc. and Subsidiaries

Consolidated Balance Sheets
December 31, 2009 and 2008

	2009	2008
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 4,198,913	$ 4,420,900
Marketable securities	—	4,100,000
Accounts receivable, net of allowances for doubtful accounts of $356,162 and $358,268, respectively	5,747,466	5,789,901
Inventories, net	4,808,240	4,678,069
Other current assets	302,948	271,069
Total current assets	15,057,567	19,259,939
PROPERTY, PLANT AND EQUIPMENT:		
Land	352,957	352,957
Buildings and improvements	3,029,126	3,017,017
Machinery and equipment	2,842,744	2,716,258
Furniture and fixtures	2,170,999	1,898,191
	8,395,826	7,984,423
Less—Accumulated depreciation	(6,556,130)	(6,135,786)
	1,839,696	1,848,637
OTHER ASSETS:		
Goodwill	870,290	870,290
Equipment on lease, net	851,800	210,743
Product license	282,936	682,936
Restricted deposits	200,995	147,149
Other assets	29,110	28,374
	2,235,131	1,939,492
Total assets	$ 19,132,394	$ 23,048,068
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 1,225,572	$ 698,693
Accrued license payable	143,690	140,062
Accrued expenses	2,695,633	3,116,755
Total current liabilities	4,064,895	3,955,510
OTHER LONG-TERM LIABILITIES:		
Deferred tax liabilities	301,692	238,200
Other long-term liabilities	1,040,122	902,551
Total other long-term liabilities	1,341,814	1,140,751
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Common stock, par value $0.01, authorized 50,000,000 shares, issued and outstanding 27,649,887 in 2009 and 2008	276,498	276,498
Additional paid-in capital	41,204,712	41,065,840
Accumulated deficit	(27,471,793)	(23,013,933)
Accumulated other comprehensive loss	(283,732)	(376,598)
Total shareholders' equity	13,725,685	17,951,807
Total liabilities and shareholders' equity	$ 19,132,394	$ 23,048,068

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, 2009 and 2008

	2009	2008
NET REVENUE	$18,401,925	$20,819,175
COST OF SALES	8,299,575	8,388,132
Gross profit	10,102,350	12,431,043
OPERATING EXPENSES:		
Selling	5,584,439	4,932,981
General and administrative	6,674,493	5,364,041
Research and development	1,793,182	1,817,047
Impairment of product license	400,000	560,000
Total operating expenses	14,452,114	12,674,069
Loss from operations	(4,349,764)	(243,026)
OTHER INCOME, NET:		
Interest income	18,760	292,231
Other income, net	37,275	253,217
Total other income, net	56,035	545,448
Income (loss) before income taxes	(4,293,729)	302,422
INCOME TAX PROVISION (BENEFIT)	164,131	106,414
Net income (loss)	$ (4,457,860)	$ 196,008
Income (loss) per share		
Basic and diluted	$ (0.16)	$ 0.01
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, 2009 and 2008

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
	Shares	Amount				
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
Comprehensive loss:						
Net loss	—	—	—	(4,457,860)	—	(4,457,860)
Translation adjustment	—	—	—	—	92,866	92,866
Comprehensive income						(4,364,994)
Stock compensation	—	—	138,872	—	—	138,872
BALANCE, December 31, 2009	27,649,887	$276,498	$41,204,712	$(27,471,793)	$(283,732)	$13,725,685

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, 2009 and 2008

	2009	2008
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$(4,457,860)	$ 196,008
Adjustments to reconcile net loss to net cash provided by operating activities—		
Depreciation and amortization	583,277	480,970
Net recovery for doubtful accounts receivable	(5,516)	(633,238)
Non-cash compensation, including fair value adjustments of liability awards	138,872	155,163
Deferred income tax provision	63,492	63,492
Impairment of product license	400,000	560,000
Changes in operating assets and liabilities:		
Accounts receivable	150,620	935,162
Inventories	(253,778)	(742,143)
Other current assets	(30,072)	99,230
Other assets	—	865,965
Accounts payable and accrued expenses	65,879	(2,727,675)
Other long-term liabilities	110,702	98,818
Net cash used in operating activities	(3,234,384)	(648,248)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Capital expenditures	(199,095)	(407,288)
Acquisition of equipment on lease	(828,220)	(184,964)
Proceeds from sales of marketable securities	4,100,000	1,925,000
Increase in restricted deposits	(50,031)	—
Net cash provided by investing activities	3,022,654	1,332,748
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	(10,257)	(164,164)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(221,987)	520,336
CASH AND CASH EQUIVALENTS, beginning of year	4,420,900	3,900,564
CASH AND CASH EQUIVALENTS, end of year	$ 4,198,913	$ 4,420,900
SUPPLEMENTAL DISCLOSURES:		
Income taxes paid	$ 20,899	$ 136,944

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 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 Pharmaceutical Industries Limited ("Teva") all of the approximately 72.3% of the outstanding shares of the Company's common stock owned by Teva, indirectly through its wholly-owned IVAX Corporation subsidiary ("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. The Debregeas-Kennedy Group currently owns approximately 72.4% of the outstanding shares of the Company's common stock.

The Company's principal source of short-term liquidity is existing cash and cash equivalents totaling $4,199,000, which the Company believes will be sufficient to meet its operating needs and anticipated capital expenditures over at least the next twelve months. In connection with the Company's evaluation of its operating results, financial condition and cash position, and specifically considering its results of operations and cash utilization during 2009, the Company has enacted, or is considering, various measures to improve its future cash flow. To this end, the Company expects operating results to improve from the operating results achieved during 2009 based principally upon increases in revenue as a result of the anticipated commercial launch, after receiving all required regulatory approvals, of the Mago® 4S in the United States and increases in international instrumentation revenue. The Company also expects operating results to improve as a result of certain initiatives it has adopted or is considering in order to reduce expenses, as well as anticipated expense reductions in 2010 as a result of the elimination of non-recurring professional fees incurred during 2009 in connection with the Company's comprehensive review of its business plans and operations with the goal of improving its competitive position. The Company is also evaluating other various forms of financing arrangements. Any such financing arrangements would likely impose positive and negative covenants, which could restrict various aspects of the Company's business, operations and finances. If the Company is not successful in improving its operating results and cash flows or if existing and possible future sources of liquidity described above are insufficient, then the Company may consider issuing debt or equity securities, incurring indebtedness or curtailing or reducing its operations.

2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

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

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and related disclosure of contingent assets and liabilities, at the date of and for the period of the financial statements. The Company's actual results in subsequent periods may differ from the estimates and judgments used in the preparation of the accompanying consolidated financial statements.

Significant estimates include the allowance for doubtful accounts, inventories, intangible assets, income and other tax accruals, warranty obligations, stock based compensation, the computation of fair-value measurements, the realization of long-lived assets and contingencies and litigation.

Recently Issued Accounting Standards

In January 2010, the FASB issued authoritative guidance intended to improve disclosure about fair value measurements. The guidance requires entities to disclose significant transfers in and out of fair value hierarchy levels and the reasons for the transfers and to present information about purchases, sales, issuances, and settlements separately in the reconciliation of fair value measurements using significant unobservable inputs (Level 3). Additionally, the guidance clarifies that a reporting entity should provide fair value measurements for each class of assets and liabilities and disclose the inputs and valuation techniques used for fair value measurements using significant other observable inputs (Level 2) and significant unobservable inputs (Level 3). This guidance is effective for interim and annual periods beginning after December 15, 2009 except for the disclosure about purchases, sales, issuances and settlements in the Level 3 reconciliation, which will be effective for interim and annual periods beginning after December 15, 2010. As this guidance provides only disclosure requirements, the adoption of this standard will not impact the Company's consolidated financial statements.

In October 2009, the FASB issued amended revenue recognition authoritative guidance for arrangements with multiple deliverables. The new authoritative guidance eliminates the residual method of revenue recognition and allows the use of management's best estimate of selling price for individual elements of an arrangement when vendor specific objective evidence ("VSOE"), vendor objective evidence ("VOE") or third-party evidence ("TPE") is unavailable. This guidance is effective for all new or materially modified arrangements entered into on or after January 1, 2011, with earlier application permitted as of the beginning of any prior fiscal year. Full retrospective application of the new guidance is optional. The Company is currently assessing the impact that the implementation of this new guidance will have on the Company's financial position and operations.

In October 2009, the FASB issued authoritative guidance which amends the scope of existing software revenue recognition accounting. Tangible products containing software components and non-software components that function together to deliver the product's essential functionality would be scoped out of the accounting guidance on software and accounted for based on other appropriate revenue recognition guidance. This guidance is effective for all new or materially modified arrangements entered into on or after January 1, 2011, with earlier application permitted as of the beginning of any prior fiscal year. Full retrospective application of the new guidance is optional. This guidance must be adopted in the same period that the Company adopts the amended accounting for arrangements with multiple deliverables described in the preceding paragraph. The Company is currently assessing the impact that the implementation of this new guidance will have on the Company's financial position and operations.

On July 1, 2009, the FASB issued the FASB Accounting Standards Codification (the "Codification"). The Codification became the single authoritative source of GAAP recognized by the FASB. The Codification superseded all previously-existing non-Securities and Exchange Commission accounting and reporting standards, and all other non-grandfathered non-Securities and Exchange Commission accounting literature not included in the Codification became nonauthoritative. The Codification was effective for interim and annual reporting periods ending after September 15, 2009. The Company adopted the Codification for the quarter ended September 30, 2009. The Company's adoption of the Codification did not have any impact on the Company's financial position and operations as this change is disclosure-only in nature.

In June 2009, the FASB issued authoritative guidance which amends the consolidation guidance applicable to variable interest entities and requires enhanced disclosures intended to provide users of financial statements with more transparent information about an enterprise's involvement in a variable interest entity. This guidance is effective beginning with the Company's consolidated financial statements for the year ending December 31, 2010 and the quarterly periods thereof. The impact of adoption was not material to the financial position and operations of the Company.

In June 2009, the FASB issued authoritative guidance which eliminates the concept of a qualifying special-purpose entity, changes the requirements for derecognizing financial assets and requires enhanced disclosure to provide financial statement users with greater transparency about transfers of financial assets, including securitization transactions and an entity's continuing involvement in and exposure to the risks related to the transfer of financial assets. This guidance is effective beginning with the Company's consolidated financial statements for the year ending December 31, 2010 and the quarterly periods thereof. The impact of adoption was not material to the financial position and operations of the Company.

In May 2009, the FASB issued amended authoritative guidance on subsequent event accounting which sets forth: (i) the period after the balance sheet date during which management of a reporting entity should evaluate events or transactions that may occur for potential recognition or disclosure in the financial statements; (ii) the circumstances under which an entity should recognize events or transactions occurring after the balance sheet date in its financial statements; and (iii) the disclosures that an entity should make about events or transactions that occurred after the balance sheet date. These guidelines were effective for interim and annual periods ending after June 15, 2009, and the Company adopted them in the quarter ended June 30, 2009. The Company has evaluated subsequent events through the date these financial statements were issued.

In April 2009, the FASB issued authoritative guidance on determining fair value when the volume and level of activity for an asset or liability has significantly decreased, and in identifying transactions that are not orderly. Based on the guidance, if an entity determines that the level of activity for an asset or liability has significantly decreased and that a transaction is not orderly, further analysis of transactions or quoted prices is needed, and a significant adjustment to the transaction or quoted prices may be necessary to estimate fair value. The guidance was effective on a prospective basis for interim and annual periods ending after June 15, 2009. The Company adopted this guidance in the quarter ended June 30, 2009. The adoption of this guidance did not have a material impact on the Company's financial position and operations.

In April 2009, the FASB issued authoritative guidance regarding interim disclosures about the fair value of financial instruments which were previously only disclosed on an annual basis. Entities are now required to disclose the fair value of financial instruments which are not recorded at fair value in the financial statements in both their interim and annual financial statements. The new requirements were effective for interim and annual periods ending after June 15, 2009 on a prospective basis. The Company adopted these requirements in the quarter ended June 30, 2009. The adoption of these requirements did not impact the Company's financial position and operations, as the requirements relate only to additional disclosures.

In April 2008, the FASB issued new authoritative guidance regarding the determination of the useful lives of intangible assets. In developing assumptions about renewal or extension options used to determine the useful life of an intangible asset, an entity needs to consider its own historical experience adjusted for entity-specific factors. In the absence of that experience, an entity shall consider the assumptions that market participants would use about renewal or extension options. The new requirements apply to intangible assets acquired after January 1, 2009. The adoption of these new rules did not have a material impact on the Company's financial position and operations.

In March 2008, the FASB issued new authoritative disclosure requirements regarding derivative instruments and hedging activities. Entities must now provide enhanced disclosures on an interim and annual basis regarding how and why the entity uses derivatives, how derivatives and related hedged items are accounted for, and how derivatives and related hedged items affect the entity's financial position, financial results and cash flows. The Company adopted these new requirements on January 1, 2009. The adoption of these new requirements did not impact the Company's financial position and operations, as they were disclosure-only in nature.

In December 2007, the FASB issued new authoritative guidance on noncontrolling interests in consolidated financial statements. This guidance requires that the noncontrolling interest in the equity of a subsidiary be accounted for and reported as equity, provides revised guidance on the treatment of net income and losses attributable to the noncontrolling interest and changes in ownership interests in a subsidiary and requires

additional disclosures that identify and distinguish between the interests of the controlling and noncontrolling owners. The Company adopted this new guidance on January 1, 2009. The adoption of this guidance did not have a material impact on the Company's financial position and operations.

In December 2007, the FASB issued revised authoritative guidance regarding business combinations. The guidance significantly changed 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 the guidance, 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. The guidance 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 was not permitted. The effect of this guidance on the Company's financial position and operations will be dependent on the nature and terms of any future business combinations that it consummates.

Cash and Cash Equivalents

The Company considers certain short-term investments in marketable debt securities with original maturities of three months or less to be cash equivalents.

Marketable 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, 2009 and December 31, 2008, the Company owned short-term marketable securities totaling $0 and $4,100,000, respectively. The Company received proceeds of $4,100,000 from the sale of short-term marketable securities owned at December 31, 2008 during the year ended December 31, 2009, and these proceeds are now invested in select money market instruments. During the year ended December 31, 2008, the Company received proceeds of $1,925,000 from the sale of marketable securities.

Prior to 2009, the Company had 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. The Dutch auction process had historically provided a liquid market for auction rate securities, as this mechanism generally allowed 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 were unable to liquidate their securities. A seller would then wait until the next successful auction to attempt to sell its auction rate securities, unless there was a secondary market for the particular securities. As a result of a failed auction, however, the auction rate securities may have, for a specified period, paid 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 have paid interest at below market rates. At such time as the interest paid on the below market rates offset the interest paid at the previously paid maximum or default contractual rate, the auction rate securities would 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 did not own, and did not invest 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. Beginning mid-February 2008, each of the remaining auction rate securities that the Company held, the par value of which was approximately $4,100,000 in the aggregate, experienced failed auctions. As a result of these failed auctions, the Company was unable during the year ended December 31, 2008 to liquidate its investment in these auction rate securities.

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 applicable accounting guidance, 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 recognized the future changes in the fair value of the Put Option in order to offset subsequent price movements of the auction rate securities. Therefore, the Company elected the fair value option set forth in the FASB guidance for fair value options for financial assets and liabilities to account for the Put Option. Under this guidance, all subsequent changes in fair value of the Put Option are 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 was 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 hierarchy (See Note 5, *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 could 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 and in some instances may take in excess of a year to collect, 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 $356,162 and $358,268 at December 31, 2009 and 2008, respectively, and activity for the years then ended was as follows:

	2009	2008
Balance at January 1	$358,268	$1,052,797
(Recovery)/provision	(5,516)	(633,238)
Write-offs	(1,168)	(54,582)
Effects of changes in foreign exchange rates	4,578	(6,709)
Balance at December 31	$356,162	$ 358,268

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. Additionally, the Company's estimates of future instrumentation and diagnostic kit product demand, or 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. 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,	
	2009	2008
Raw materials	$ 707,054	$ 783,186
Work-in-process	1,070,964	1,019,564
Finished goods	3,030,222	2,875,319
Total inventories, net	$4,808,240	$4,678,069

In accordance with our inventory accounting policy, total inventories at December 31, 2009 include components for current or future versions of products and instrumentation, including approximately $260,000 in Mago® 4S instrumentation and instrument components in anticipation of the future commercial product launch. On September 30, 2009, the Company filed a 510(k) premarket submission with the U.S. Food and Drug Administration (the "FDA") for the Mago® 4S, its next-generation fully automated Enzyme-linked Immunosorbent Assay ("ELISA") system for autoimmune and infectious disease testing that the Company intends to market in the United States. The Company has received feedback from the FDA requesting that the Company provide additional analytics and clinical test data, and the Company is working with the FDA to provide the requested information and expedite the approval process. Inventory amounts at December 31, 2009 also included approximately $200,000 of inventory relating to the Company's hepatitis product, substantially all of which has a shelf life exceeding five years, which is currently pending regulatory approval based upon the Company's January 2008 submission requesting "CE Marking" in the European Union (See Note 4, *Product License, Including Impairment Charge).* At December 31, 2008, Mago® 4S instrumentation and instrument components inventories was approximately $150,000 and hepatitis related inventory was $195,000.

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 $397,235 and $351,136 during the years ended December 31, 2009 and 2008, 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,	
	2009	2008
Equipment on lease, at cost	$6,219,021	$6,328,661
Less—Accumulated amortization	5,367,221	6,117,918
	$ 851,800	$ 210,743

Equipment on lease is typically amortized over three or five years. Amortization expense related to equipment on lease was $186,042 and $129,834 for the years ended December 31, 2009 and 2008, respectively.

Long Lived Assets Including Goodwill

The changes in the carrying amount of goodwill are as follows:

	2008	2009
Balance as of January 1,		
Goodwill	$ 6,722,725	$ 6,722,725
Accumulated impairment losses	(5,852,435)	(5,852,435)
Goodwill acquired during the year	—	—
Impairment losses recorded during the year	—	—
Balance as of December 31,	$ 870,290	$ 870,290

As discussed in Note 3, *Impairment of Long Lived Assets including Goodwill*, 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. In assessing the recoverability of goodwill and other intangibles, the Company makes assumptions regarding, among other things, estimated future cash flows, including current and projected levels of income, success of research and development projects, discount rates and terminal growth rates, business trends, prospects and market conditions, to determine the fair value of the respective assets. If these or other estimates or their related assumptions change in the future, impairment charges may be required to record impairment charges for these assets not previously recorded. There were no impairment charges to goodwill recorded during 2009 or 2008.

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 4, *Product License, Including Impairment Charge,* the Company tests its product license for possible impairment. During the fourth quarter of 2009, 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 $400,000, reducing the value of the product license to $282,936 as of December 31, 2009, from $682,936 as of December 31, 2008. 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.

Restricted Deposits

Long-term restricted deposits of $200,995 and $147,149 at December 31, 2009 and 2008, respectively, consist primarily of cash deposits required as part of the sales tender process with governmental customers in Italy.

Foreign Currencies

The Company's operations include operations that are located in Italy and the Company is working to increase its presence in other international markets. 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, and this risk may increase in the future as a result of the Company's efforts to increase its international presence. 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, 2009 and 2008 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 estimates. 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, 2009 and 2008.

At December 31, 2009, the Company had stock-based employee compensation plans as described in Note 10, *Shareholders' Equity*. The Company recorded total compensation expense related to unvested options of $138,872 and $155,163 for the years ended December 31, 2009 and December 31, 2008, respectively.

Comprehensive Loss

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

	Year Ended December 31,	
	2009	2008
Net income (loss)	$(4,457,860)	$ 196,008
Foreign currency translation adjustment	92,866	(373,847)
Comprehensive loss	$(4,364,994)	$(177,839)

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 income (loss) per share computation for the years ended December 31, 2009 and 2008 is as follows:

	Year Ended December 31,	
	2009	2008
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	1,130,116	1,127,249

3 IMPAIRMENT OF LONG-LIVED ASSETS INCLUDING GOODWILL

The FASB guidance for goodwill and other intangible assets uses 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. The Company had total goodwill of $870,290 as of December 31, 2009 and 2008, all of which 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 required in the 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, 2009 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 3% and a discount rate of 23%, no impairment was noted in 2009. 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.

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, declines in the Company's market capitalization could potentially require additional impairment charges to be recorded in future periods for the remaining goodwill for ImmunoVision.

4 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 $143,690 is included in accrued license payable in the accompanying consolidated balance sheet as of December 31, 2009. The Company continues to work 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. Based upon amended regulatory standards adopted by the applicable notifying body during the fourth quarter of 2009 that the Company must now comply with in order to receive approval, the Company now expects "CE Marking" granting approval for the last of the eleven products covered under the license agreement, and the payment of the remaining license payable, to be delayed until either the fourth quarter of 2010 or the first quarter of 2011, with the product launch of these hepatitis test kits being delayed until the first quarter of 2011.

During the fourth quarter of 2009, 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 $400,000, reducing the value of the product license to $282,936 as of December 31, 2009, from $682,936 as of December 31, 2008. Fair value was determined based upon the income approach, which estimates fair value based upon future discounted cash flows. Based upon amended regulatory standards adopted by the applicable notifying body during the fourth quarter of 2009 that the Company must now comply with in order to receive approval, 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 six years and revenue and gross margin estimates beginning in 2011, a range of potential outcomes was determined and weighted based upon an estimated probability of occurrence. Estimated future cash flows generated by the technology granted by the product license was then calculated using a discount rate of 30%, reflecting the Company's best estimate of fair value. If further product approval delays beyond the product launch assumptions included in the Company's discounted cash flow computations occur, then the Company may be required to record an additional impairment charge with respect to all or a portion of the remaining $282,936 intangible product license of hepatitis technology asset.

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. The methodology and assumptions utilized to compute the 2008 non-cash impairment

charge were similar to the methodology and assumptions described above to compute the non-cash impairment charge recorded in the fourth quarter of 2009, except that, with respect to the 2008 fair value determination, the Company utilized a discount rate of 20% and a forecasted cash flow period of seven years.

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.

5 FAIR VALUE MEASUREMENT

Effective January 1, 2008, the Company adopted authoritative FASB guidance regarding fair value measurements. This accounting guidance 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 and 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 accounting guidance, 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) at December 31, 2009 and December 31, 2008:

December 31, 2009	Fair Value	Level 1	Level 2	Level 3
Cash equivalents:				
Money market funds	$2,943,532	$2,943,532	$—	$ —
Total financial assets	$2,943,532	$2,943,532	$—	$ —

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
Rights (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,* under the heading *Marketable Securities*, 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

6 CONCENTRATION OF CREDIT RISK

The Company performs periodic credit evaluations of its customers' financial condition and provides allowances for doubtful accounts as required. The Company's accounts receivable are generated from sales made primarily in the United States and Italy. As of December 31, 2009 and 2008, $4,050,898 and $3,890,358, respectively, of total net accounts receivable were due in Italy. At December 31, 2009 and 2008, 48.1% and 50.9%, 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 *Accounts Receivable and Allowance for Doubtful Accounts*).

As referenced in Note 2, *Summary of Significant Accounting Policies* under the heading *Marketable 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.

7 INCOME TAXES

The Company's 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, 2009 and 2008, 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, 2009 and 2008, the Company had net deferred tax liabilities of $301,692 and $238,200, respectively, relating to tax deductible goodwill. Additionally, as of December 31, 2009 and 2008, 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 European operation, and additional allowances have been provided for losses occurring since that date through December 31, 2009. 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,	
	2009	2008
Current:		
Domestic	$ —	$ —
Foreign	82,480	42,922
Deferred:		
Domestic	63,492	63,492
Foreign	18,159	—
Total	$164,131	$106,414

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

	Year Ended December 31,	
	2009	2008
Domestic	$(2,946,877)	$246,146
Foreign	(1,346,852)	56,276
Total	$(4,293,729)	$302,422

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

	December 31, 2009	December 31, 2008
Current:		
Accounts receivable allowances	$ 117,547	$ 149,352
Reserves and accruals	308,191	411,130
Capitalized inventory costs	143,209	146,827
Valuation allowance	(568,947)	(707,309)
Deferred income taxes	—	—
Long-Term:		
Depreciation and basis differences on fixed and intangible assets	345,785	573,912
Stock based compensation	239,299	185,833
Other	(20,583)	(21,980)
Foreign net operating losses	1,560,585	1,609,242
Domestic net operating losses	4,649,982	3,536,083
Valuation allowance	(6,755,068)	(5,883,090)
Net deferred tax asset	$ —	$ —

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

	December 31, 2009	December 31, 2008
Long-Term:		
Tax deductible goodwill	301,692	238,200
Net deferred tax liability	$301,692	$238,200

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, 2009	Year Ended December 31, 2008
Provision (benefit) for income taxes at U.S. Federal statutory rate of 35%	$(1,502,805)	$105,848
Change in valuation allowance (excluding portion relating to stock options)	1,083,032	(66,428)
Foreign tax rate differential	409,525	(1,961)
Global permanent differences	174,379	68,955
Provision (benefit) for income taxes	$ 164,131	$106,414

The Company's income tax provision or benefit for the years ended December 31, 2009 and 2008 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 $11,923,000, of which $3,543,000 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, $72,000 and $2,680,000 are available for use prior to their expirations in 2022,

2023, 2024, 2025, 2026, 2027 and 2029, respectively, subject to any applicable limitations as described below. Approximately $3,708,000 of the domestic net operating loss at December 31, 2009, representing approximately $1,447,000 of the valuation allowance ($0 for the years ended December 31, 2009 and 2008) 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 2010.

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. As a result of that acquisition, the Company's ability to utilize net operating loss carryforwards to offset any future taxable income is currently limited to $900,000 per year, plus both any limitation unused since the acquisition and any unused net operating losses generated after the September 2, 2008 acquisition date. The amount of the annual limitation will be adjusted upwards for any recognized built-in gains on certain assets sold during the five year period commencing with the ownership change. The limitations of these net operating loss carryforwards did not impact the Company's results for the year ended December 31, 2009.

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, 2009, the 2006-2008 tax years remain subject to examination by major tax jurisdictions. At December 31, 2009 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.

8 EMPLOYEE BENEFIT PLAN

The Company has a 401(k) employee savings plan which allows for pre-tax employee payroll contributions and discretionary employer matching contributions. Matching contributions of $86,747 and $71,600 were made into this plan during the years ended December 31, 2009 and 2008, respectively.

9 ACCRUED EXPENSES AND OTHER LONG-TERM LIABILITIES

Accrued expenses consist of the following:

	December 31,	
	2009	2008
Payroll costs	$ 794,135	$1,191,749
Taxes, other than income taxes	1,250,892	1,106,603
Professional fees	215,822	293,563
Royalties	74,198	86,548
Other	360,586	438,292
	$2,695,633	$3,116,755

Other long-term liabilities consist of the following:

	December 31,	
	2009	2008
Italian employee leaving indemnity[1]	$ 977,112	$865,583
Other	63,010	36,968
	$1,040,122	$902,551

(1) Italian law provides that each employee is entitled to receive a payment upon their departure from the Company. The amount vests immediately and is adjusted for inflation.

10 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 2009 and 2008, 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.

Equity Incentive Plans

At the 2009 Annual Meeting of Stockholders of the Company, held on June 3, 2009, the Company's stockholders approved the Company's 2009 Equity Incentive Plan (the "2009 Plan"). The 2009 Plan is the successor plan to both of the Company's previously adopted equity incentive compensation plans—the 1999 Performance Equity Plan (the "Performance Plan") and the 1999 Stock Option Plan (the "1999 Plan," and together with the Performance Plan, collectively, the "Prior Plans"). As a result of the approval of the 2009 Plan, the Company will not make any future grants under the Prior Plans. In addition to the 1,561,072 shares of the Company's common stock that remained available for grant from the Prior Plans prior to the June 3, 2009 Annual Meeting of Stockholders, an additional 2,000,000 shares of common stock were authorized for grant under the 2009 Plan.

The Company's Performance Plan was created on September 30, 1999 upon approval by the Board of Directors and stockholders of b2bstores.com. The Performance Plan authorized the grant of up to 2,000,000 shares of common stock of the Company to key employees, officers, directors and consultants. As a result of the approval of the 2009 Plan, the Company will not grant any additional awards 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 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, 2009 and changes during the years ended December 31, 2009 and 2008 under the Performance Plan, and, after its adoption and approval, the 2009 Plan for options granted by the Company:

	Number of Shares	Weighted Average Exercise Price
Outstanding at December 31, 2007	784,949	$3.66
Granted	475,000	$0.79
Expired	(131,000)	$2.96
Terminated	(1,700)	$3.79
Outstanding at December 31, 2008	1,127,249	$2.55
Granted	200,000	$0.42
Expired	(75,900)	$2.08
Terminated	(121,233)	$1.78
Exercised	—	—
Outstanding at December 31, 2009	1,130,116	$2.27

	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
$0.37 - $0.47	200,000	9.4	$0.42	200,000	$0.42
$0.50 - $0.65	275,000	8.7	$0.59	275,000	$0.59
$1.00	100,000	7.6	$1.00	100,000	$1.00
$1.20	100,000	8.8	$1.20	—	—
$1.56	100,000	6.7	$1.56	100,000	$1.56
$4.35 - $4.91	150,000	5.5	$4.37	150,000	$4.37
$5.20 - $7.12	205,116	1.2	$6.28	205,116	$6.28
	1,130,116	6.8	$2.27	1,030,116	$2.38

The aggregate intrinsic value for the outstanding and exercisable in-the-money options was $19,000 at December 31, 2009.

A summary of the status of the Company's non-vested options as of December 31, 2009 and changes during the year ended December 31, 2009 is presented below:

Non-vested Options	Number of Shares	Weighted Average Grant-date Fair Value
Outstanding at December 31, 2008	305,000	$0.52
Granted	200,000	$0.34
Vested	(355,000)	$0.45
Terminated	(50,000)	$0.46
Exercised	—	—
Outstanding at December 31, 2009	100,000	$0.46

As of December 31, 2009, there was $10,000 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 0.2 years. No windfall tax benefits were recognized during the years ended December 31, 2009 or 2008.

11 SEGMENT INFORMATION

The Company's management reviews financial information, allocates resources and manages its business by geographic region. The domestic region, which includes corporate expenditures, contains the Company's subsidiaries in the United States. The European region contains the Company's subsidiary located in Italy. The information provided is based on internal reports and was developed and utilized by management to track 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, 2009 and 2008:

	Domestic	European	Eliminations	Total
December 31, 2009:				
External net sales	$12,545,155	$ 5,856,770	$ —	$18,401,925
Intercompany sales	836,821	72,440	(909,261)	—
Net revenue	$13,381,976	$ 5,929,210	$ (909,261)	$18,401,925
Loss from operations	$ (3,031,814)	$(1,337,377)	$ 19,427	$ (4,349,764)
Assets	$11,260,272	$ 7,872,122	$ —	$19,132,394
Goodwill	$ 870,290	$ —	$ —	$ 870,290
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

12 COMMITMENTS AND CONTINGENCIES

Leases

Certain of the Company's office, plant and warehouse facilities are leased by the Company under non-cancelable operating leases. Rent expense for the years ended December 31, 2009 and 2008 totaled $495,000 and $544,000, respectively. The future minimum lease payments under non-cancelable capital leases and their related assets recorded at December 31, 2009 and 2008 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, 2009 were as follows:

2010	$ 520,000
2011	487,000
2012	422,000
2013	345,000
2014	17,000
Thereafter	—
Total minimum lease payments	$1,791,000

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.

13 QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following table summarizes selected quarterly data of the Company for the years ended December 31, 2009 and 2008 (in thousands except per share data):

2009	First Quarter	Second Quarter	Third Quarter	Fourth Quarter[1]	Full Year
Net revenue	$4,719	$ 4,661	$ 4,562	$ 4,460	$18,402
Gross profit	2,773	2,473	2,432	2,424	10,102
Loss from operations	(399)	(1,590)	(1,117)	(1,244)	(4,350)
Net loss	(465)	(1,510)	(1,157)	(1,326)	(4,458)
Basic and diluted net loss per share	(0.02)	(0.05)	(0.04)	(0.05)	(0.16)
2008					
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

(1) Includes the effects of the write-offs of portions of the value of the Company's product license of hepatitis technology during each of the years ended December 2009 and 2008, as discussed in Note 4, *Product License, Including Impairment Charge.*

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, 2009.

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, 2009 that would have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

The following table sets forth information with respect to our directors and our executive officers as of March 26, 2010.

Name	Age	Position
Charles R. Struby, Ph.D.	60	Chief Executive Officer and President
Kevin D. Clark	47	Chief Operating Officer
Steven E. Lufkin	47	General Manager
Mark S. Deutsch	47	Chief Financial Officer and Vice President—Finance
Patrice R. Debregeas	66	Chairman of the Board of Directors
Paul F. Kennedy	65	Director
Jerry C. Benjamin	69	Director
John B. Harley, M.D., Ph.D.	60	Director
Laurent Le Portz	43	Director
Lawrence G. Meyer	69	Director

Set forth below are the names, ages, positions held and business experience, including during the past five years, of our directors and our executive officers as of March 26, 2010. In addition, the information set forth below with respect to each director includes the specific experience, qualifications, attributes and/or skills of the director which, in the opinion of our Board of Directors, qualifies him to serve as a director and are likely to enhance the Board of Directors' ability to manage and direct our business and affairs. 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 60, 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 47, 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. Steven E. Lufkin, age 47, was appointed our General Manager in January 2010. Prior to joining us, Mr. Lufkin served as Chief Executive Officer of DxTech, LLC, a multi-national early stage medical diagnostics company, which Mr. Lufkin founded in 2005. During his time with DxTech, Mr. Lufkin was responsible for all aspects of DxTech's business, related joint ventures, organizational development, technology partnerships and original fund raising, and he transitioned the company from its original investors to ownership by a $2 billion hedge fund. Among his other accomplishments at DxTech, was the establishment of global joint ventures and partnerships that resulted in technology acquisitions, research partnerships and new commercial channels. From 2000 to 2005, Mr. Lufkin served as President of MRI Ventures, a wholly owned subsidiary of Midwest Research Institute, where he directed technology and strategic business development efforts, focused on the development and execution of growth strategies, and significantly increased research operations. He began his career at Aventis Pharmaceuticals and its predecessor companies in several capacities, including product manager, manager of business information, sales management and field sales representative. During December 2009, DxTech filed a voluntary petition for relief under Chapter 7 of the United States Bankruptcy Code. DxTech made such filing with the consent of DxTech Holdings, the controlling member of DxTech and a wholly-owned subsidiary of an affiliate of the Laurus family of funds, and in alignment with the wrap-up on the applicable Laurus fund.

Mr. Mark S. Deutsch, age 47, 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 over 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.

Mr. Patrice R. Debregeas, age 66, 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. As a successful entrepreneur with over 40 years of experience in leading companies within the life sciences industry, our Board of Directors believes that Mr. Debregeas brings strategic insight and leadership and a wealth of knowledge regarding the life sciences industry to the Board. Our Board of Directors also believes that Mr. Debregeas' global experience contributes greatly to the Board's composition and may prove to be a valuable resource with respect to our goal to increase our presence in key countries in Europe, among other regions.

Mr. Paul F. Kennedy, age 65, 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. Our Board of Directors believes that Mr. Kennedy's history as a strong operating executive with a strategic background and his operational experience in the life sciences industry contribute valuable insight to the Board. Our Board of Directors also believes that Mr. Kennedy's insights and experience as a senior executive of complex multinational life sciences companies, such as Cozart and Novo Nordisk France, will be valuable in helping to guide us in the years ahead.

Mr. Jerry C. Benjamin, age 69, has served as a director since October 2008. From 1985 to 2008, Mr. Benjamin was a General Partner of Advent Venture Partners, a venture capital management firm located in London which focuses on venture and growth investment in the life sciences and technology industries. Since 2008, Mr. Benjamin has been serving as Senior Advisor to Advent Venture Partners. 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. Our Board of Directors believes that Mr. Benjamin brings to the Board key insights gained through his vast experience as a director of companies within the life sciences industry and that, as an established officer of a venture capital management firm focused on the life sciences and technology industries, Mr. Benjamin brings strategic insight to the Board with respect to our business as well as emerging technologies and business models. Through these experiences, Mr. Benjamin has also developed a keen appreciation for audit and financial control related issues and, therefore, is a valuable asset to the Audit Committee of our Board of Directors.

Dr. John B. Harley, age 60, 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 (2000 to 2004), George Lynn Cross Research Professor (1999 to present), Associate Professor (1986 to 1992) and Assistant Professor (1982 to 1986). Since 1996, Dr. Harley has been an Adjunct Professor in the Department of Pathology. In the Department of Microbiology, Dr. Harley has served as Adjunct Professor (1992 to present), Adjunct Associate Professor (1988 to 1992) and Adjunct Assistant Professor (1983 to 1988). Since 1982, Dr. Harley has also been associated with the Oklahoma Medical Research Foundation's Arthritis and Immunology Program as Program Head (1999 to present), Member (1998 to present), Associate Member (1989 to present), Affiliated Associate Member (1986 to 1989) and Affiliated Assistant Member (1982 to 1986). Dr. Harley has also served as a Staff Physician (1982, 1984 to 1987 and 1992 to present) and a Clinical Investigator (1987 to 1992), Immunology Section, Medical Service at the Veterans Affairs Medical Center, Oklahoma City, Oklahoma. In 1981 and 1982, Dr. Harley was a Postdoctoral Fellow in Rheumatology with the Arthritis Branch of the National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases, National Institute of Health, Bethesda, Maryland. He was also a Clinical Associate at the Laboratory of Immunoregulation, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland from 1979 to 1982. Dr. Harley is 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. As the longest tenured member of our Board of Directors, Dr. Harley brings an unparalleled depth of experience in the medical diagnostics sector combined with an intimate knowledge of our operational, financial and strategic development. In addition, our Board of Directors believes that Dr. Harley's strong academic background and medical research history, particularly within the medical diagnostics field, further contributes to the strategic composition of the Board.

Mr. Laurent Le Portz, age 43, has served as a director since September 2008. Since November 2009, Mr. Le Portz has been a Partner of Alma Partners, a company specializing in equity investments in distressed companies for turnaround situations. 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. With vast experience in investment management on a global basis and an established track record of success, our Board of Directors believes that Mr. Le Portz adds valuable expertise and insight to the Board. In addition, Mr. Le Portz' strong finance and strategic background makes him a valuable asset to our Board and Audit Committee.

Mr. Lawrence G. Meyer, age 69, 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. Our Board of Directors believes that Mr. Meyer brings a compelling set of attributes that enhance the diversity and composition of the Board and provide him with a unique perspective with respect to our business and affairs. In addition, Mr. Meyer's experience as a practicing attorney provides our Board of Directors with a valuable resource when certain events which require legal attention or expertise arise and that his previous service as a director of a number of development pharmaceutical firms allows him to contribute valuable insight to the Board.

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, 2009.

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 and Laurent Le Portz. 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—2009

The following table sets forth certain summary information concerning compensation which, during the fiscal years ended December 31, 2009 and 2008, 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, 2009, 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, 2009 (collectively, the "Named Executive Officers").

Name and Principal Position	Year	Salary	Bonus	Stock Awards	Option Awards[4]	Non-Equity Incentive Plan Compensation[5]	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Charles R. Struby, Ph.D.,[1]	2009	$234,932	$25,000	—	$30,000	—	—	—	$289,932
Chief Executive Officer	2008	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Paul F. Kennedy,[2]	2009	—	—	—	—	—	—	—	—
Former Chief Executive Officer	2008	$ 83,334	—	—	—	—	—	$16,666	$100,000
Kevin D. Clark,[3]	2009	$227,000	—	—	—	—	—	$35,796[6]	$262,796
Chief Operating Officer and Former Acting Chief Executive Officer	2008	$227,000	—	—	$48,200	$146,833	—	—	$422,033
Mark S. Deutsch,	2009	$159,075	—	—	—	—	—	$21,108[6]	$180,183
Chief Financial Officer	2008	$151,500	—	—	$48,200	$109,083	—	—	$308,783

(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 and, accordingly, he did not receive any compensation from us during the year ended December 31, 2008. 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.

(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. Because we accrued the entire amount of such payment during the year ended December 31, 2008, in accordance with the rules and regulations of the Securities and Exchange Commission, all $100,000 of such payment is reported in the table above as compensation paid to Mr. Kennedy during the year ended December 31, 2008, notwithstanding the fact that a portion of such amount was related to his service as our Chief Executive Officer, President and Chairman of the Board from January 1, 2009 through January 23, 2009. 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. During 2009, Mr. Kennedy was paid an annual cash retainer of $20,000 for his service on our Board of Directors. As such payment was made to Mr. Kennedy in consideration for his services as our director and not as our officer or employee, such amount is not included in the table above but rather is included in the "Director Compensation—2009" table below.

(3) Throughout the fiscal years ended December 31, 2008 and 2009, Mr. Clark served as, and Mr. Clark continues to serve as, our Chief Operating Officer and the Chief Operating Officer of ImmunoVision. In addition, Mr. Clark served as our acting Chief Executive Officer from January 10, 2008 through September 22, 2008. 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, 2008 through January 9, 2008 and the period from September 23, 2008 through December 31, 2009, 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 and (b) 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. 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.

(4) On December 16, 2009, the Securities and Exchange Commission amended certain of its executive compensation and corporate governance disclosure rules. In relevant part, the amendment requires disclosure of the aggregate grant date fair value of option awards calculated in accordance with Codification Topic 718, *Compensation—Stock Compensation*, rather than the dollar amount recognized for financial statement purposes for the fiscal year, as previously required. In accordance with the amendment, this table includes the aggregate grant date fair value of option awards granted during the year ended December 31, 2009, as well as of option awards granted during the year ended December 31, 2008 (which, as required by the amendment, have been adjusted from previously reported amounts). Assumptions used in the calculation of these amounts are included in Note 10 to our Consolidated Financial Statements, *Shareholders' Equity*.

(5) The amounts for 2008 are comprised of payments made under a retention bonus plan to Mr. Clark in the amount of $113,500 and Mr. Deutsch in the amount of $75,750 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 well as a $33,333 payment made to each of Messrs. Clark and Deutsch under our executive officer incentive plan for the year ended December 31, 2008 upon the achievement of pre-established operating income goals. We did not adopt an executive officer incentive plan or similar plan for the year ended December 31, 2009.

(6) The amounts for 2009 are comprised of payments made to Messrs. Clark and Deutsch for unused, accumulated vacation days for which they had not been previously compensated for years prior to and including 2009.

Outstanding Equity Awards at Fiscal Year-End—2009

The following table sets forth certain information regarding equity-based awards held by the Named Executive Officers as of December 31, 2009.

	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.	100,000	—	—	$0.37	3/26/19
Paul F. Kennedy	—	—	—	—	—
Kevin D. Clark	50,000	—	—	$0.65	9/22/18
	—	50,000(1)	—	$1.20	9/22/18
Mark S. Deutsch	5,116	—	—	$7.12	3/17/11
	10,000	—	—	$4.35	7/13/15
	50,000	—	—	$0.65	9/22/18
	—	50,000(1)	—	$1.20	9/22/18

(1) These options vested on March 23, 2010, but they are included as unexercisable options because they were not exercisable as of December 31, 2009. As a result of their vesting on March 23, 2010, these options are currently exercisable.

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. 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. Dr. Struby's current annual base salary is $250,000. 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 NYSE 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 our Board or Compensation Committee. Dr. Struby did not receive an annual cash bonus for his services as our Chief Executive Officer and President during 2009. 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.

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. Mr. Clark's current annual base salary is $227,000. 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. Mr. Clark did not receive an annual cash bonus for his services as our Chief Operating Officer during 2009. 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 paid Mr. Kennedy a one time lump-sum payment of $100,000, $83,334 of which related 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 was 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 was conditioned upon, among other things, Mr. Kennedy selling at least 1.5 million shares of our common stock to Patrice R. 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 also reimbursed Mr. Kennedy for approximately $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.

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 practice of compensating directors who are deemed to be "independent" under the NYSE Amex rules relating to the independence of directors for their service on the Board, Audit Committee and Compensation Committee, on June 15, 2009, (i) each of our directors who was deemed to be "independent" under the NYSE Amex rules relating to the independence of directors was granted, in consideration for his service on the Board, an annual cash retainer of $20,000, payable in four equal quarterly installments, (ii) each member of the Audit Committee was granted, in consideration for his service on such committee, an annual cash

retainer of $7,500, payable in four equal quarterly installments, (iii) each member of the Compensation Committee was granted, in consideration for his service on such committee, an annual cash retainer of $5,000, payable in four equal quarterly installments, and (iv) each of our directors who was deemed to be "independent" under the NYSE 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 2009 Equity Incentive Plan with an exercise price of $0.47 per share, which was the closing price of our common stock on the NYSE Amex on the grant date, and which fully vested immediately upon grant.

Historically, directors who were not deemed to be "independent" under the NYSE 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 NYSE Amex rules relating to the independence of directors.

Director Compensation—2009

The following table sets forth certain information regarding the compensation paid to our directors for their service during the fiscal year ended December 31, 2009.

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards[1]	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Jerry C. Benjamin	$27,500	—	$9,500	—	—	—	$ 37,000
Patrice R. Debregeas	$20,000	—	—	—	—	—	$ 20,000
John B. Harley, M.D., Ph.D.	$25,000	—	$9,500	—	—	$ 39,000[2]	$ 73,500
Paul F. Kennedy	$20,000	—	—	—	—	—	$ 20,000
Laurent Le Portz	$32,500	—	$9,500	—	—	—	$ 42,000
Lawrence G. Meyer	$28,750	—	$9,500	—	—	$119,000[3]	$157,250

(1) Represents the aggregate grant date fair value of option awards calculated in accordance with Codification Topic 718, *Compensation—Stock Compensation*. Assumptions used in the calculation of these amounts are included in Note 10 to our Consolidated Financial Statements, *Shareholders' Equity*. The table below sets forth, as of December 31, 2009, the aggregate number of stock options held by each of our directors:

Name	Stock Options
Jerry C. Benjamin	50,000
Patrice R. Debregeas	—
John B. Harley, M.D., Ph.D.	140,000
Paul F. Kennedy	—
Laurent Le Portz	50,000
Lawrence G. Meyer	50,000

(2) Represents the aggregate dollar amount earned by Dr. Harley during 2009 under that certain oral consulting agreement between Dr. Harley and ImmunoVision, pursuant to which Dr. Harley was paid $2,000 per month through July 2009, and is being paid $5,000 per month thereafter, to provide ImmunoVision with technical guidance and business assistance on an as-needed basis.

(3) Represents the aggregate dollar amount earned by Mr. Meyer during 2009 in consideration for his provision of certain legal services which he provided to us during the year on an as-needed basis.

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

Security Ownership of Certain Beneficial Owners and Management

The following table indicates, as of March 26, 2010, information about the beneficial ownership of our common stock by (1) each director as of March 26, 2010, (2) each Named Executive Officer, (3) all directors and executive officers as of March 26, 2010 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	14,376,313	52.0%
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%
Charles R. Struby, Ph.D.	100,000[5]	*
Kevin D. Clark	191,340[6]	*
Mark S. Deutsch	133,116[7]	*
Jerry C. Benjamin	50,000[8]	*
John B. Harley, M.D., Ph.D.	140,000[9]	*
Laurent Le Portz	50,000[10]	*
Lawrence G. Meyer	60,000[11]	*
All directors and executive officers as of March 26, 2010 as a group (10 persons)	20,825,769[12]	73.5%

* 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 20,026,313, or 72.4%, 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) Includes options for 100,000 shares of common stock granted to Dr. Struby.

(6) Includes options for 100,000 shares of common stock granted to Mr. Clark, and 70,540 shares of common stock owned by Mr. Clark through our 401(k) Plan.

(7) Includes options for 115,116 shares of common stock granted to Mr. Deutsch.

(8) Includes options for 50,000 shares of common stock granted to Mr. Benjamin.

(9) Includes options for 140,000 shares of common stock granted to Dr. Harley.

(10) Includes options for 50,000 shares of common stock granted to Mr. Le Portz.

(11) Includes options for 50,000 shares of common stock granted to Mr. Meyer.

(12) Includes options for 75,000 shares of common stock granted to Steven E. Lufkin, who was appointed our General Manager during January 2010.

Equity Compensation Plan Information

The following table sets forth information, as of December 31, 2009, 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	1,130,116	$2.27	3,471,072
Equity compensation plans not approved by stockholders	0	$—	0
Total	1,130,116	$2.27	3,471,072

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

Controlling Stockholder

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. The Debregeas-Kennedy Group currently owns approximately 72.4% of the outstanding shares of our common stock.

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.

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 was paid $2,000 per month through July 2009, and is being paid $5,000 per month thereafter, to provide ImmunoVision with technical guidance and business assistance on an as-needed basis (in addition to the amounts he receives for his service as a member of our Board of Directors and Compensation Committee). 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. During 2009, we paid JK Autoimmunity an aggregate of $10,000 under such license.

In determining that Mr. Meyer is independent, our Board of Directors considered the fact that Mr. Meyer provides certain legal services to us on an as-needed basis and, during 2009, received an aggregate of $119,000 in consideration for his provision of such legal services. Our Board of Directors also considered the fact that Mr. Meyer has agreed that he will continue to earn $119,000 annually from us for his provision of legal or other services to us (in addition to the amounts he receives for his service as a member of our Board of Directors and Compensation Committee).

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, 2009 and 2008.

	For the years ended December 31,	
	2009	2008
Audit Fees	$377,700	$336,000
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	7,000
Total Fees	$377,700	$343,000

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, 2009 and 2008

Consolidated Statements of Operations for the years ended December 31, 2009 and 2008

Consolidated Statements of Shareholders' Equity for the years ended December 31, 2009 and 2008

Consolidated Statements of Cash Flows for the years ended December 31, 2009 and 2008

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	Incorporated by reference to our Form 10-K filed on March 30, 2009.
10.4*	Employment Agreement, dated as of March 27, 2009, by and between IVAX Diagnostics, Inc. and Kevin Clark	Incorporated by reference to our Form 10-K filed on March 30, 2009.

Exhibit Number	Description	Method of Filing
10.5*	Employment Agreement, dated as of January 4, 2010, by and between IVAX Diagnostics, Inc. and Steven E. Lufkin	Filed herewith.
10.6	1999 Performance Equity Plan	Incorporated by reference to our Form SB-2 filed on October 6, 1999.
10.7	1999 Stock Option Plan	Incorporated by reference to our Form 10-K filed on April 1, 2002.
10.8	2009 Equity Incentive Plan	Incorporated by reference to our Schedule 14A filed on May 8, 2009.
10.9	Form of Nonqualified Stock Option Agreement (Employee)	Incorporated by reference to our Form 8-K filed on June 16, 2009.
10.10	Form of Nonqualified Stock Option Agreement (Independent Director)	Incorporated by reference to our Form 8-K filed on June 16, 2009.
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 31, 2010

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 31, 2010
/s/ MARK S. DEUTSCH **Mark S. Deutsch**	Chief Financial Officer and Vice President-Finance (Principal Financial Officer) (Principal Accounting Officer)	March 31, 2010
/s/ PATRICE R. DEBREGEAS **Patrice R. Debregeas**	Chairman of the Board of Directors	March 31, 2010
/s/ PAUL F. KENNEDY **Paul F. Kennedy**	Director	March 31, 2010
/s/ JERRY C. BENJAMIN **Jerry C. Benjamin**	Director	March 31, 2010
/s/ JOHN B. HARLEY, M.D., PH.D. **John B. Harley, M.D., Ph.D.**	Director	March 31, 2010
/s/ LAURENT LE PORTZ **Laurent Le Portz**	Director	March 31, 2010
/s/ LAWRENCE G. MEYER **Lawrence G. Meyer**	Director	March 31, 2010

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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, but not limited to, our distribution and other strategic agreements and other initiatives designed to improve our performance in the future), including, without limitation, the risk that such strategic initiatives may not result in increased levels of sales, expand our global presence, product offerings or technology platforms in the U.S. or international markets, further our growth, better position us to meet the changing demands of existing and potential customers, improve our profitability or otherwise enhance our competitive position in the health care industry, improve our operating results, financial condition or cash position or otherwise, individually or in the aggregate, result in the benefits which we expect to derive from such initiatives, and the risk that, in order to implement and attempt to achieve our strategic initiatives, we may find it necessary to obtain financing, whether from issuing debt or equity securities, incurring indebtedness or otherwise, and that any such financing may not be available on acceptable terms or at all; the risks and uncertainties associated with our compliance with FDA and other applicable regulations and requirements, including, without limitation, that, notwithstanding the results of the recent audit conducted by the FDA of our Miami manufacturing facility, we may not be in compliance with all FDA regulations and requirements and that our compliance with FDA and other applicable regulations and requirements in the future cannot be assured; the risks and uncertainties relating to the Mago® 4 and Mago® 4S, including, without limitation, that we may not receive regulatory approval for the Mago® 4S when expected, or at all, that the Mago® 4S may not be available when expected, or at all, and that the Mago® 4 and/or the Mago® 4S may not perform as expected or otherwise result in improved operating results; the risk that the reorganization of our operations may not successfully break down silos or otherwise better position us to meet our goals in the future; the risk that our hiring of a General Manager may not result in improvements in our global sales and marketing operations or improvements with respect to our regulatory activities; the risk that we may not successfully maximize our operating efficiencies and resulting cost competitiveness and/or identify and secure additional strategic collaborations in the future, notwithstanding our Chief Operating Officer's focus on our research and development, and production and business development; the risk that, even if we are successful in identifying and securing additional strategic collaborations in the future, such collaborations may not further our growth or otherwise improve our operating results, financial condition or cash position; the risk that growth trends in the health care industry may not continue and that, even if such trends do continue, we may not be able to take advantage of such trends or otherwise become a recognized presence in the health care industry; 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, 2009 which has been provided as a portion of this annual report. Many of these risks and factors are beyond our control.

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