IVAX Diagnostics, Inc.

2010 Annual Report

IVAX Diagnostics, Inc.

April 18, 2011

To Our Stockholders:

We are grateful to our stockholders who have had confidence in IVAX Diagnostics through the three changes in our majority ownership in the past five fiscal years. While we admittedly face economic challenges, we believe that there are also exciting new opportunities to expand our businesses and to increase stockholder value.

During 2010, we made significant progress toward putting together all of the pieces of the puzzle, from our expanded product menu to our enhanced instrumentation systems both in the United States and internationally. However, during 2010, our net revenues decreased to $17.0 million from $18.4 million in 2009, and our net loss was $4.2 million compared to $4.5 million in 2009. We expect to continue to incur losses from operations for the foreseeable future.

Our cash and cash equivalents totaled $1.8 million at December 31, 2010 compared to $4.2 million at December 31, 2009. We have had negative cash flow during each of the past five fiscal years, other than in 2008, during which fiscal year I had the opportunity and pleasure to serve as IVAX Diagnostics' then Acting Chief Executive Officer for a period of ten months. We do not believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements over the next twelve months. Unfortunately, our economic situation resulted in our audited consolidated financial statements for 2010, included in our Annual Report on Form 10-K which was filed with the Securities and Exchange Commission on March 30, 2011, containing a report from our independent registered public accounting firm that indicates there is substantial doubt about our ability to continue as a going concern. In addition to the contemplated investment described below, we are evaluating various forms of financing arrangements, including incurring indebtedness, such as through a bank loan. However, the ongoing turmoil in the equity and credit markets and current market conditions have limited the size, type and availability of financing arrangements, such as bank loans, to us and have made the terms and conditions of several types of financing arrangements unattractive, or altogether unavailable, to us. Our economic situation has fostered a re-evaluation of our business plan and our place in the diagnostics industry going forward.

On September 1, 2010, ERBA Diagnostics Mannheim GmbH purchased all of the approximately 72% of the outstanding shares of our common stock then held by our prior majority stockholder group for $0.75 per share, or an aggregate purchase price of approximately $15 million. ERBA Diagnostics Mannheim remains convinced of the

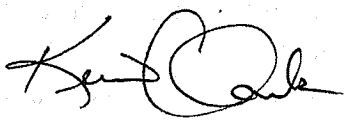
potential for the long-term success of IVAX Diagnostics. As we had previously announced, on April 8, 2011, ERBA Diagnostics Mannheim entered into a stock purchase agreement with us pursuant to which ERBA Diagnostics Mannheim has agreed to purchase from us, and we have agreed to sell and issue to ERBA Diagnostics Mannheim, 20 million shares of our common stock at a purchase price of $0.75 per share, or an aggregate purchase price of $15 million and warrants to purchase an additional 20 million shares of our common stock at an exercise price of $0.75 per share. This investment was approved by a committee of our Board of Directors composed solely of independent directors who together comprise a majority of our Board of Directors. This investment is conditioned upon us obtaining all required approvals of our stockholders, including, without limitation, the approval of holders of at least 66⅔% of the issued and outstanding shares of our common stock (excluding any shares beneficially owned, directly or indirectly, by ERBA Diagnostics Mannheim). We currently intend to use the net proceeds of this investment for general corporate purposes, including funding the continued growth and development of IVAX Diagnostics' businesses and working capital requirements. The availability of the net proceeds of this investment is also expected to put us in a position to be more nimble and prepared for acquisitions and other strategic opportunities; however, we do not currently have any definitive agreements or binding commitments to make any future acquisitions.

On January 25, 2011, we received clearance from the United States Food and Drug Administration on the 510(k) premarket submission that we had filed for the Mago® 4S, our new proprietary instrumentation system that has expanded menu capabilities and can perform both ELISA and IFA techniques simultaneously. Since our receipt of regulatory approval of the Mago® 4S, we have received a positive response from our customers, as we have placed, or are in the process of placing, and have pending orders to sell, a number of these instruments to new and established customers.

Looking ahead into the remainder of 2011, we expect to continue our cost containment efforts, in particular with regard to manufacturing efficiencies, and we also expect to implement a number of initiatives in an effort to improve sales. We expect our commercial launch of the Mago® 4S in the United States, our expanded reagent menu and our expanded geographical distribution network to have a positive impact on our operating results in 2011.

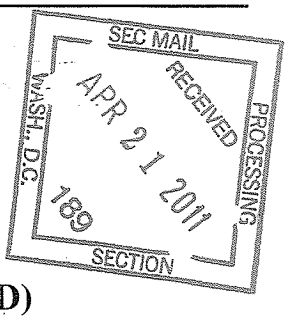
We are enthusiastic about the future of IVAX Diagnostics and we look forward to sharing our progress with you.

Sincerely,



Kevin D. Clark,
Chief Executive Officer,
Chief Operating 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, 2010

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, 2010, was approximately $3,902,000 computed by reference to the price at which the common equity was last sold on the NYSE Amex on such date.

As of March 25, 2011, there were 27,649,887 shares of common stock outstanding.

Documents Incorporated by Reference:

None.

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® 4S, Mago® Plus and Aptus® systems, include a fully-automated ELISA processor operating with our own user-friendly software, which allows customers to perform tests in an automated mode. In 2009, we updated the Mago® Plus instrument to include the capability to process ELISA and ImmunoFluorescent Assay, or IFA, simultaneously. In the fourth quarter of 2009, we completed the development of, received European regulatory approvals for, and began non-domestic 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. The Mago® 4 offers 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. In 2010, we continued the development of a variation of the Mago® Plus, named the Mago® 4S, for the market in the United States. The Mago® 4S also performs both ELISA and IFA techniques simultaneously. In January 2011, we received the required 510(k) regulatory clearance for the Mago® 4S and we have recently begun to market the instrument in the United States. Accordingly, we currently expect to begin commercial deliveries of the Mago® 4S during the first quarter of 2011. We also develop, manufacture and market raw materials, such as antigens used in the production of diagnostic kits.

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

Delta, which IVAX Corporation, 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 and Mago® Plus systems, which include hardware, reagents and software. Delta completed development of the Mago® 4S during 2010, and is expected to also manufacture the Mago® 4S. The market trend for in vitro diagnostic products is towards increased laboratory automation that allows laboratories to improve their efficiencies and lower cost. We believe that our proprietary Mago® 4, Mago® 4S, Mago® Plus and Aptus® systems should enable laboratories to achieve increased automation in the test sectors in which we compete. The Mago® 4, Mago® Plus and Aptus® systems, in association with over 200 specific ELISA-based and IFA 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. During the year ended December 31, 2010, approximately 70% of Delta's revenue generated from

customers in Italy was revenue from government owned hospitals and the remaining 30% was 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 or distributes over 200 assays that the United States Food and Drug Administration, or FDA, has cleared. Our autoimmune product line consists of over 150 ELISA test kits and over 50 IFA assays that the FDA has cleared. These products 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. 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 then 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.

On September 1, 2010, ERBA Diagnostics Mannheim GmbH, or ERBA, an in vitro diagnostics company headquartered in Germany, the parent company of which is Transasia Bio-Medicals Ltd., or Transasia, purchased all of the approximately 72.4% of the outstanding shares of our common stock then owned by the Debregeas-Kennedy Group for an aggregate purchase price of approximately $15,000,000, or $0.75 per share. As a result of this share acquisition, ERBA now beneficially owns, directly or indirectly, approximately 72.5% of the outstanding shares of our common stock.

Market. In vitro diagnostics, which involves the detection of diseases, conditions or infections from fluid or tissue samples from the human body, has evolved into one of the fastest growing diagnostics markets in the world. Today, immunoassays associated with in vitro diagnostics are essential to the practice of health care worldwide and represent the second largest segment of the in vitro diagnostics market. These tests have been contributing significantly to clinical laboratory work since the 1960s, and driving the total in vitro diagnostics market over the last few decades. Future growth prospects for immunoassays remain promising, thanks to the steady expansion in potential applications in clinical diagnostics, incremental technological improvements such as greater accuracy, sensitivity, result turnaround times and portability, user friendliness and rising demand for quality healthcare services from an expanding base of aging population. 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 estimate the United States market for in vitro diagnostics was $16.7 billion in 2010 and estimated to grow at a compound annual growth rate of 5.4% from 2011 to 2015. Our focus is specifically centered on the immunoassay segment of in vitro diagnostics. By product segment, the enzyme immunoassay systems market continues to remain the largest and the fastest growing product segment in the global immunoassay systems market, by value. Estimated at approximately $3.7 billion in 2009, the enzyme immunoassay systems market is projected to grow at a compound annual growth rate of approximately 4.8% from 2011 to 2015. Our focused effort remains on the market for autoimmune and infectious disease immunoassay products. The autoimmune and infectious disease immunoassay market has been growing steadily at a compound annual growth rate of 7.1% for the past three years and analyst predictions estimate the size of the market to reach $326 million by 2013.

Research and Development. We devote substantial resources for research and development. We incurred $1.8 million in 2009 and $1.6 million in 2010 for research and development activities. Our research and development efforts have been targeted primarily towards the development of the Mago® 4 and Mago® 4S. Both products have now received regulatory approval. We are continuing our research and development in 2011, both for making improvements to the Mago® 4 and Mago® 4S as well as planning for the next-generation instrument. We also plan to expand the menu of test kits we offer in the autoimmune and infectious disease testing sectors and we are considering entering additional diagnostic test sectors.

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, primarily 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 a bid process known as 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. The autoimmune and infectious disease market is comprised of more than 10 competitors. However, many of the competitors in the marketplace utilize contract manufacturing to bring their products to market. We are one of only three competitors in the autoimmune and infectious disease market that vertically integrate the manufacturing process from raw material through production and regulatory approval. We believe this vertical integration also affords us the possibility to expand our business by contract and raw material manufacturing relationships.

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 are much larger and have significantly greater financial, technical, manufacturing, sales and marketing resources than us. According to industry analysts, approximately 16 companies account for an approximately 86% market share of the total global 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 the autoimmune sector, 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. Our competitors include, among others, Siemens Medical Solutions, 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.

We are seeking to differentiate ourselves from our competitors through our proprietary instruments and reagent systems. We believe our vertically integrated model affords us economic and development advantages over our competition. In bringing new automated systems and reagent products to market, we expect to successfully differentiate our product offering. Through increased reagent system development, we expect to effectively increase our market opportunity and share through these developments. In an effort to supplement our proprietary products, we entered into an agreement with Dynex Technologies in 2008. This agreement allows us to distribute their DSX™ and DS2™ instrument systems in conjunction with our test kits on a worldwide basis.

Personnel. As of March 1, 2011, we had approximately 106 full time employees, of whom 7 were managerial, 56 were technical and manufacturing, 14 were administrative and 29 were sales, marketing and service.

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

Aptus® instrument is no longer manufactured. The Mago® Plus instrument has been our primary product. In the future, we expect that the Mago® 4, Mago® 4S and other 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. 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 at least one other device that was introduced into the marketplace prior to May 1976, or one other legally marketed device that is not subject to pre-market approval. 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, even though 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.

Our most recent audit report includes an explanatory paragraph indicating substantial doubt about our ability to continue as a going concern.

While our consolidated financial statements included in this Annual Report on Form 10-K have been prepared assuming that we will continue as a going concern, substantial doubt has arisen about our ability to continue as a going concern. The independent auditors' report issued in conjunction with our consolidated financial statements for the year ended December 31, 2010 contains an explanatory paragraph indicating that certain matters raise substantial doubt about our ability to continue as a going concern. In addition, we have included going concern disclosure in Note 2 to our consolidated financial statements included in this Annual Report on Form 10-K, which states that certain matters raise substantial doubt about our ability to continue as a going concern and which addresses the substantial doubt about our ability to continue as a going concern. We cannot guarantee that we can generate net income, increase revenues, improve our cash flow or successfully obtain debt or equity financing on acceptable terms, or at all, and, if we cannot do so, then we may not be able to survive and any investment in our company may be lost.

We need to raise additional funds in the future to fund our operations, and these funds may not be available on acceptable terms or at all.

As of December 31, 2010, we had available to us approximately $1.8 million in cash and cash equivalents. We do not believe that our existing cash and cash equivalents will be sufficient to meet our anticipated cash requirements over the next twelve months. Our ability to continue as a going concern is dependent upon receiving additional funds through the issuance of debt or equity securities or incurring indebtedness, successfully implementing our business plan and strategic initiatives and improving our cash flow. There is no assurance that debt or equity financing, if and when required, will be available on acceptable terms, or at all. If we are unable to raise needed capital on terms acceptable to us, then we may not be able to develop new products, enhance our existing products, execute our business plan, take advantage of future opportunities or

respond to competitive pressures or unanticipated customer requirements, and we may be required to curtail or reduce our operations. Any of these events could materially and adversely affect our business, prospects, operating results, financial condition and 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, 2010, we recorded net revenues of $17.0 million and net loss of $4.2 million. For the year ended December 31, 2009, we recorded net revenues of $18.4 million and net loss of $4.5 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. 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 and 2010, we have enacted various measures to improve future cash flow. To this end, we expect operating results to improve from the operating results achieved during 2010 based principally upon increases in revenue as a result of our commercial launch of the Mago® 4S in the United States and increases in United States and international revenue from new channels of distribution. We also expect operating results to improve as a result of certain initiatives we have adopted, or are considering adopting, in order to reduce expenses. We are also evaluating various forms of debt and equity 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. In addition, any issuance of equity securities, or securities convertible into shares of our common stock, would be dilutive to our existing stockholders. 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 as well as possible sources of debt and equity financings. 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 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.

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 have developed 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 marketed only outside of the United States. We have developed a variation of the Mago® Plus, named the Mago® 4S, which we intend to market in the United States. During the first quarter of 2011, we received clearance from the FDA on the 510(k) premarket submission that we filed for the Mago® 4S. Accordingly, we have begun to market and make commercial deliveries in the United States. 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® 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 more 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. The timeframe during which we had expected to begin marketing hepatitis test kits manufactured at our facility in Italy was delayed following the conclusion of an inspection conducted in 2009 by the applicable notifying body required to obtain "CE Marking" and a related meeting with the applicable notifying body during which we were informed that our filing requires additional clinical data. There have been further delays in 2010 due to additional information requests. 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 strategy, 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.

Since the fourth quarter of 2007, we have focused on the development of the Mago® 4 and Mago® 4S as a platform for marketing our kits. 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. Based on the delay during 2009 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, 2010, we had approximately $0.3 million of intangible assets and approximately $0.1 million of accrued payables relating to the hepatitis technology

product license. There were further delays in 2010 due to additional information requests. The delays during 2009 and 2010, 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.

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, 2010, our total inventories included $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 release of 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.

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® 4S, Mago® 4, Mago® Plus and Aptus® instruments 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 2010, we incurred approximately $1.6 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. 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, administrative or other similar 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 the conclusion of an inspection conducted in 2009 by the applicable notifying body required to obtain "CE Marking" for our hepatitis test kits, and a related meeting with the applicable notifying body during which we were informed that our filing requires additional clinical data, we concluded that the product launch of our hepatitis test kits would 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. At December 31, 2010, we had approximately $0.3 million of intangible assets and approximately $0.1 million of accrued payables relating to the hepatitis technology product license. There were further delays in 2010 due to additional information requests. 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 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 2009 or 2010. 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 a bid process known as 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 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. 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, 2010 and 2009, our accounts receivable were $5.7 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, 2010 and 2009, $4.1 million and $4.2 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. Of the consolidated net accounts receivable, approximately 48%, or $2,586,000, at December 31, 2010 and 38%, or $2,174,000, at December 31, 2009 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, 2010 and 2009, Delta represented 30.5% and 31.8%, 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, South America and Asia. 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, 2010 and 2009, 30.5% and 31.8%, 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.

A significant portion of our cash and cash equivalents are held at a single brokerage firm.

A significant portion of our cash and cash equivalents are presently held at one international securities brokerage firm. Accordingly, we are subject to credit risk if this brokerage firm is unable to repay the balance

in the account or deliver our securities or if the brokerage firm should become bankrupt or otherwise insolvent. Any of the above events could have a material and adverse effect on our business and financial condition.

ERBA may be deemed to control our company.

ERBA beneficially owns, directly or indirectly, approximately 72.5% 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, ERBA, 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. Suresh Vazirani, the Chief Executive Officer of ERBA, currently serves as executive Chairman of our Board of Directors, and Kishore "Kris" Dudani, the Marketing and Business Development Representative — South, Central and Latin America, of ERBA, currently serves as a member of our Board of Directors. Transasia is the parent company of ERBA.

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 the NYSE Amex (formerly known as the American Stock Exchange) since March 15, 2001. Because ERBA beneficially owns, directly or indirectly, approximately 72.5% 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 may make it more difficult for our stockholders to sell their shares, and which may make the trading price of our common stock subject to price volatility.

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:

- our ability to continue as a going concern;
- 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;
- the dilutive impact of any equity securities, or securities convertible into shares of our common stock, which we may issue in the future;
- the restrictions imposed by any positive or negative covenants to which we may become subject under indebtedness which we may incur in the future;
- 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 ability of the Mago® 4S to perform as expected;
- the impact of the commercial release of the Mago® 4S on the judgments and estimates we have made with respect to our financial condition, operating results and cash flows;
- the impact on our financial condition and operating results of making or changing judgments and estimates as a result of future design changes to, or the development of improved instrument versions of, the Mago® 4 or Mago® 4S or as a result of future demand for the Mago® 4 or Mago® 4S;
- the ability of the Mago® 4 or Mago® 4S to be a source of revenue growth for us;
- our ability to receive financial benefits or achieve improved operating results as a result of the commercial release of the Mago® 4 or 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 market the DSX™ and DS2™ instrument systems from Dynex Technologies in conjunction with our test kits on a worldwide basis;
- the success of our comprehensive review of our business plans and operations and the initiatives that we have implemented or may 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 comprehensive review of our business plans and operations and the initiatives that we have implemented or may implement based on the results of such review;
- 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, South America, Asia 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;
- our ability to utilize our net operating losses, whether subject to limitations or not, and its impact on our financial condition and operating results;
- the impact of any future limitations on our ability to utilize our net operating losses in the event of any future change in control or similar transaction;
- 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 financial condition, operating results and cash flows;
- our production capacity at our facility in Miami, Florida;
- our ability to successfully improve our facilities and upgrade or replace our equipment and information systems in the timeframe and utilizing the amount of funds anticipated or at all;
- our dependence on 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;
- 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 a significant portion 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;
- voting control of our common stock by ERBA;
- conflicts of interest with ERBA and its affiliates, including Suresh Vazirani and/or Kishore "Kris" Dudani, and with our officers, employees and other directors; 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 50,000 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 25, 2011, there were approximately 118 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 2010 and 2009, as reported by the NYSE Amex:

2010	High	Low
Fourth Quarter	$ 0.61	$0.52
Third Quarter	0.72	0.51
Second Quarter	0.80	0.42
First Quarter	0.75	0.41
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

We did not declare or pay cash dividends on our common stock during 2010 or 2009, 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 F-1 to F-28 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.

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 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 then 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.

On September 1, 2010, ERBA Diagnostics Mannheim GmbH, or ERBA, an in vitro diagnostics company headquartered in Germany, the parent company of which is Transasia Bio-Medicals Ltd., or Transasia, purchased all of the approximately 72.4% of the outstanding shares of our common stock then owned by the Debregeas-Kennedy Group for an aggregate purchase price of approximately $15,000,000, or $0.75 per share. As a result of this share acquisition, ERBA now beneficially owns, directly or indirectly, approximately 72.5% of the outstanding shares of our common stock.

RESULTS OF OPERATIONS

YEAR ENDED DECEMBER 31, 2010 COMPARED TO THE YEAR ENDED DECEMBER 31, 2009

OVERVIEW

Net loss totaled $4,215,000 in 2010 compared to net loss of $4,458,000 in 2009. Operating loss was $4,173,000 in 2010 compared to operating loss of $4,350,000 in 2009. The reduction in both net loss and loss from operations in 2010 compared to 2009 resulted primarily from reductions in all categories of operating expenses, partially offset by declines in revenues and gross profit. Net revenues decreased by $1,370,000 to $17,032,000 in 2010 from $18,402,000 in 2009, consisting of a decrease in net revenues from domestic operations of $707,000, from $12,545,000 in 2009 to $11,838,000 in 2010, and a decrease in net revenues from European operations of $664,000, including the effect of exchange rate fluctuations of the United States dollar relative to the Euro, from $5,857,000 in 2009 to $5,193,000 in 2010. Gross profit decreased by $1,283,000 to $8,819,000 in 2010 from $10,102,000 in 2009, primarily as the result of the abovementioned decline in net revenues. Gross profit as a percentage of net revenues decreased to 51.8% during 2010 from 54.9% during 2009, principally as a result of lower absorption of fixed manufacturing costs due to lower reagent sales volume and an increase in the sale of instruments, which have a lower average margin than reagent sales.

Operating expenses decreased to $12,992,000 in 2010 from $14,452,000 in 2009 as a result of decreases in all operating expense categories. Comparing 2010 to 2009, selling expenses decreased by $682,000, general and administrative expenses decreased by $224,000, research and development expenses decreased by $154,000. In addition, we recorded a non-cash impairment charge of $400,000 in 2009, while no impairment charges were recorded in 2010.

NET REVENUES AND GROSS PROFIT

	2010	2009	Period over Period Increase (Decrease)
Net Revenues			
Domestic	$11,839,000	$12,545,000	$ (706,000)
European	5,193,000	5,857,000	(664,000)
Total	17,032,000	18,402,000	(1,370,000)
Cost of Sales	8,213,000	8,300,000	87,000
Gross Profit	$ 8,819,000	$10,102,000	$(1,283,000)
% of Total Net Revenues	51.8%	54.9%	

Net revenues in 2010 decreased by $1,370,000, or 7.4%, from 2009. This decrease was comprised of decreases of $706,000 in net revenues from domestic operations and $664,000 in net revenues from European operations. Contributing to the decline in net revenues is the effect of a decrease of $254,000 in net revenues from European operations due to fluctuation of the United States dollar relative to the Euro, as further discussed in "Currency Fluctuations" below. As measured in Euros, net revenues from European operations in 2010 decreased by 4.0% compared to 2009. The decrease in net revenues from European operations was principally due to volume declines in Italy (mainly with regard to Italian public customers, partially offset by an increase in sales to private laboratories) as well as volume declines in other international markets. Net revenues from domestic operations in 2010 decreased by 5.6% compared to 2009. The decrease in net revenue from domestic operations was primarily due to declines in volumes of reagent sales.

Gross profit in 2010 decreased by $1,283,000, or 12.8%, 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 decrease in gross profit as a percentage of net revenues to 51.8% in 2010 from 54.9% in 2009 resulted mainly from lower absorption of fixed manufacturing costs due to lower reagent sales volume and an increase in the sale of instruments, which have a lower average margin than reagent sales.

OPERATING EXPENSES

	2010	% of Revenue	2009	% of Revenue	Period over Period Decrease
Selling					
Domestic	$ 2,964,000	17.4%	$ 3,631,000	19.7%	$ (667,000)
European	1,938,000	11.4%	1,953,000	10.6%	(15,000)
Total	4,902,000	28.8%	5,584,000	30.3%	(682,000)
General and Administrative	6,451,000	37.9%	6,675,000	36.3%	(224,000)
Research and Development	1,639,000	9.6%	1,793,000	9.7%	(154,000)
Impairment of Product License	—		400,000	2.2%	(400,000)
Total Operating Expenses	$12,992,000	76.3%	$14,452,000	78.5%	$(1,460,000)

The decrease of $682,000 in selling expenses was due to reductions in domestic expenses for labor, sales commissions, consulting fees and travel expenses. Sales commissions are impacted by actual sales.

The decrease of $224,000 in general and administrative expenses was due principally to decreases in consulting fees, other professional fees and domestic repair and maintenance, partially offset by an increase in severance costs in the United States and Europe compared to those incurred in 2009.

The decrease in research and development expenses of $154,000 was due principally to the decrease in research and development expenses in Europe following the regulatory approval and commercial release of the Mago® 4, partially offset by increases in domestic labor and contract labor costs related to the regulatory approval process for the Mago® 4S, particularly in the latter part of 2010.

During 2009, we recorded a non-cash impairment charge of $400,000 relating to the value of our product license of hepatitis technology. Although progress was made during 2009 to meet the requirements specified in July 2009 by the applicable notifying body to obtain "CE Marking," amended regulatory standards adopted by

the applicable notifying body during the fourth quarter of 2009 (with which we must comply in order to receive regulatory approval) required us to revise 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. Based upon this methodology, and considering the impact of global economic conditions, we recorded this non-cash product license impairment charge to operations in 2009. There were no similar charges recorded in 2010.

LOSS FROM OPERATIONS

Loss from operations totaled $4,173,000 in 2010 as compared to loss from operations of $4,350,000 in 2009. Loss from operations in 2010 was composed of a $2,582,000 loss from domestic operations and a $1,591,000 loss from European operations. 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 $1,337,000 loss from European operations. Domestic operations include corporate expenditures, including costs required to maintain our status as a public company.

OTHER INCOME, NET

Total other income, net for 2010 aggregates to approximately $70,000, including the net proceeds of approximately $220,000 of a cash grant awarded to us, less currency exchange losses, recurring banking fees and one-time fees related to arrangements with a leasing company. During the fourth quarter of 2010, we received the cash grant discussed above. This cash grant was awarded to us under the Qualifying Therapeutic Discovery Projects Program (Section 48D of the Internal Revenue Code, which was enacted as part of the Patient Protection and Affordable Care Act of 2010) in connection with therapeutic discovery projects relating to the Mago® 4S and certain diagnostic Enzyme-linked Immunosorbent Assay and Immunofluorescence Assay test kits.

Interest income decreased from $19,000 in 2009 to $4,000 in 2010 due to lower average cash balances during 2010 and continued low rates of interest on money market funds.

INCOME TAX PROVISION

We recorded income tax provisions of $111,000 during 2010 and $164,000 during 2009. 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 2010 and 2009 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 tax benefit was recorded during 2009 and 2010 on our losses because we had a full valuation allowance against the net deferred income tax assets.

NET LOSS

We generated a net loss of $4,215,000 in 2010 as compared to a net loss of $4,458,000 in 2009. Our basic and diluted loss per common share was $0.15 in 2010 as compared to a basic and diluted loss per common share of $0.16 in 2009. The net loss for both years resulted primarily from the various factors discussed above. See Note 3, *Summary of Significant Accounting Policies*, in the Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for a description of the calculation of loss per common share.

LIQUIDITY AND CAPITAL RESOURCES

While our consolidated financial statements included in this Annual Report on Form 10-K have been prepared assuming that we will continue as a going concern, substantial doubt has arisen about our ability to continue as a going concern. The independent auditors' report issued in conjunction with our consolidated financial statements for the year ended December 31, 2010 contains an explanatory paragraph indicating that certain matters raise substantial doubt about our ability to continue as a going concern. In addition, we have included going concern disclosure in Note 2 to our consolidated financial statements included in this Annual Report on Form 10-K, which states that certain matters raise substantial doubt about our ability to continue as a going concern and which addresses the substantial doubt about our ability to continue as a going concern.

We cannot guarantee that we can generate net income, increase revenues, improve our cash flow or successfully obtain debt or equity financing on acceptable terms, or at all, and, if we cannot do so, then we may not be able to survive and any investment in our company may be lost. We are evaluating various forms of debt and equity 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. In addition, any issuance of equity securities, or securities convertible into shares of our common stock, would be dilutive to our existing stockholders. 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 as well as possible sources of debt and equity financings. 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 be required to curtail or reduce our operations.

At December 31, 2010, our working capital was $7,081,000 compared to $10,993,000 at December 31, 2009. Cash and cash equivalents totaled $1,827,000 at December 31, 2010 and $4,199,000 at December 31, 2009.

Net revenues in 2010 were significantly lower than in 2009, which has resulted in loss from operations of $4,173,000 in 2010. Net cash flows of $1,883,000 were used in operating activities during 2010 as compared to $3,234,000 that were used in operating activities during 2009. Cash used in operating activities during 2010 was primarily the result of the net loss of $4,215,000 partially offset by non-cash items of $1,090,000 and changes in operating assets and liabilities of $1,242,000. The non-cash items include depreciation and amortization, non-cash compensation, a provision for doubtful accounts receivable, a reduction of the allowance for inventory obsolescence and deferred income taxes. Cash provided by changes in operating assets and liabilities was primarily due to a decrease of $749,000 in inventories, a decrease of $151,000 in other current assets and an increase of $316,000 in accounts payable and accrued expenses. 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, a provision for inventory obsolescence 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.

Net cash of $368,000 was used in investing activities during 2010 as compared to $3,023,000 that was provided by investing activities during 2009. The decrease in cash flows relating to investing activities in 2010 was due principally to capital expenditures of $269,000 and acquisition of equipment on lease of $72,000. 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 had invested at their par value of $4,100,000 as a result of our exercise of rights we received from UBS. In 2009, cash was utilized for the acquisition of equipment on lease for $828,000 and for capital expenditures of $199,000, partially offsetting the increase from sale of marketable securities.

During 2010, we acquired equipment aggregating $222,000 under a capital lease and repaid approximately $38,000 during the year. There were no financing activities during 2009.

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

Our product research and development expenditures were approximately $1,600,000 in 2010 and may be higher during 2011 in our domestic operations at least temporarily as we validate additional test kits for the recently released Mago® 4S and in our European operations as we continue instrument development. 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 $300,000 to $500,000 will be required in 2011 to improve and expand our facilities, equipment and information systems. The amount required will depend, among other things, on the extent and timing of increases in production at our Miami facility.

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 2010, we have enacted, or are considering enacting, various measures to improve future cash flow. To this end, we expect operating results to improve from the operating results achieved during 2010 based principally upon increases in revenue as a result of our commercial launch, having received all required regulatory approvals, of the Mago® 4S in the United States, and increases in the United States and international revenue from new channels of distribution.

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, 2010, 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, the realization of long-lived assets 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. We believe the following critical accounting policies and the judgments and estimates we make concerning their application have significant impact on our consolidated financial statements.

REVENUE RECOGNITION

A principal source of revenue is our "reagent rental" program in which customers make reagent kit purchase commitments with us that will usually last for a period of three to five years. In exchange, we typically include an instrument system, which remains our property (or, in the case of a lease financing arrangement, that of the financing company). 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 based on historical loss percentages 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 $399,000 and $356,000 as of December 31, 2010 and December 31, 2009, respectively.

INVENTORY

We regularly review inventory quantities on hand, which include components for current or future versions of products and instrumentation. If necessary, we record a provision for excess and obsolete inventory based primarily on our estimates of component obsolescence, product demand and production requirements, as well as based upon the status of a product within the regulatory approval process. In accordance with our inventory accounting policy, our inventory balance at December 31, 2010 included components for current or future versions of products and instrumentation.

Our inventory balance as of December 31, 2010 included approximately $200,000 of inventory relating to our hepatitis product, substantially all of which has a shelf life exceeding five years, which is currently pending regulatory approval based upon our January 2008 submission requesting "CE Marking" in the European Union. Based upon amended regulatory standards adopted by the applicable notifying body during the fourth quarter of 2009 with which we must now comply in order to receive regulatory approval and additional requirements specified during 2010 by the applicable notifying body, we now expect "CE Marking" granting regulatory approval for the remaining products covered under the license agreement and product launch by the fourth quarter of 2011. At December 31, 2009, Mago® 4S instrumentation and instrument component inventories were approximately $260,000 and hepatitis related inventories were approximately $200,000. The Mago® 4S received regulatory approval in January 2011 and therefore the related inventory is no longer considered a future version.

Inventory reserves were $452,000 and $499,000 as of December 31, 2010 and December 31, 2009, respectively.

GOODWILL AND OTHER INTANGIBLES

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. All of our goodwill is currently recorded at ImmunoVision, one of our domestic subsidiaries. Although we consider our current market capitalization, we do 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. However, the continued decline in our market capitalization could also potentially require us to record additional impairment charges in future periods for the remaining $870,000 of goodwill 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 Euros 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 is not expected to be paid until we receive "CE Marking" approval from the European Union for our hepatitis products.

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. 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. 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 to obtain "CE Marking" with which we must now comply in order to receive regulatory approval and additional requirements specified during 2010 by the applicable notifying body, 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, estimated future cash flows generated by the technology granted by the product license was then calculated, 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 the hepatitis technology asset.

STOCK-BASED COMPENSATION

Stock-based compensation expense for all stock-based compensation awards is based on the grant-date fair value estimate 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 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 expected term, taking into account 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 losses from domestic 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 European operations, we have provided a full valuation allowance against our deferred tax assets as of December 31, 2010. 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 amount or a portion of the 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 1, 2010 acquisition by ERBA of the approximately 72.4% of the outstanding shares of our common stock previously owned by the Debregeas-Kennedy Group. As a result of that acquisition, our ability to utilize net operating loss carryforwards to offset future taxable income is currently limited to approximately $825,000 per year, plus both any limitation unused since the acquisition and any unused net operating losses generated after the September 1, 2010 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 September 1, 2010 ownership change, but may be further limited in the event of any future change in control or similar transaction. Our results for 2010 and 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

Refer to Note 3, *Summary of Significant Accounting Policies,* under the heading *Recently Issued Accounting Standards*, to our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for further information regarding recently issued accounting standards applicable to us.

CURRENCY FLUCTUATIONS

For the years ended December 31, 2010 and 2009, approximately 30.5% and 31.8%, 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, Asia 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 $254,000 in net revenues in 2010 compared to 2009. Our European subsidiary incurs most of its revenue and expenses in Euro, which, to some extent, serves as a natural hedge and limits the net currency exposure.

During the years ended December 31, 2010 and 2009, 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.

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 $111,000 for the year ended December, 31, 2010 compared to $164,000 for the year ended December 31, 2009. Our income tax provisions for the years ended December 31, 2010 and 2009 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. 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 2010 and 2009 was a result of Italian local income taxes based upon applicable statutory rates effective in Italy.

As of December 31, 2010, 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, 2010, we had net deferred tax liabilities of $365,000 relating to tax deductible goodwill at ImmunoVision, and we recorded a corresponding deferred

tax provision of $63,000 in 2010. 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 ability to use our net operating loss carryforwards will be limited in the future as a result of the September 1, 2010 acquisition by ERBA of the approximately 72.4% of the outstanding shares of our common stock previously owned by the Debregeas-Kennedy Group. As a result of that acquisition, our ability to utilize net operating loss carryforwards to offset future taxable income is currently limited to approximately $825,000 per year, plus both any limitation unused since the acquisition and any unused net operating losses generated after the September 1, 2010 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 September 1, 2010 ownership change, but may be further limited in the event of any future change in control or similar transaction. Our results for 2010 and 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

Board of Directors
IVAX Diagnostics, Inc.

We have audited the accompanying consolidated balance sheet of IVAX Diagnostics, Inc. (a Delaware corporation) and subsidiaries as of December 31, 2010, and the related consolidated statements of operations, stockholders' equity and comprehensive loss, and cash flows for the year ended December 31, 2010. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit 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. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of IVAX Diagnostics, Inc. and subsidiaries as of December 31, 2010, and the results of their operations and their cash flows for the year ended December 31, 2010 in conformity with accounting principles generally accepted in the United States of America.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2, the Company incurred a net loss of $4,214,679 during the year ended December 31, 2010, and used cash from operations of $1,882,867 during the year ended December 31, 2010. These factors, among others, as discussed in Note 2 to the consolidated financial statements, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Grant Thornton LLP

Miami, Florida
March 30, 2011

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 the results of their operations and their cash flows for the year then ended 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 audit. We conducted our audit of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

PricewaterhouseCoopers LLP
Philadelphia, Pennsylvania
March 31, 2010

IVAX Diagnostics, Inc. and Subsidiaries
Consolidated Balance Sheets
December 31, 2010 and 2009

ASSETS	2010	2009
CURRENT ASSETS:		
Cash and cash equivalents	$ 1,826,228	$ 4,198,913
Accounts receivable, net of allowances for doubtful accounts of $399,376 and $356,162, respectively	5,344,205	5,747,466
Inventories, net	4,077,896	4,808,240
Other current assets	146,366	302,948
Total current assets	11,394,695	15,057,567
PROPERTY, PLANT AND EQUIPMENT:		
Land	352,957	352,957
Buildings and improvements	3,062,569	3,029,126
Machinery and equipment	3,124,767	2,842,744
Furniture and fixtures	1,997,371	2,170,999
	8,537,664	8,395,826
Less accumulated depreciation	(6,919,528)	(6,556,130)
	1,618,136	1,839,696
OTHER ASSETS:		
Goodwill	870,290	870,290
Equipment on lease, net	679,438	851,800
Product license	282,936	282,936
Restricted deposits	228,680	200,995
Other assets	26,847	29,110
	2,088,191	2,235,131
Total assets	$ 15,101,022	$ 19,132,394
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 1,597,555	$ 1,225,572
Capital lease obligation, current	71,826	—
Accrued license payable	132,521	143,690
Other accrued expenses	2,511,698	2,695,633
Total current liabilities	4,313,600	4,064,895
OTHER LONG-TERM LIABILITIES:		
Capital lease obligation, noncurrent	100,612	—
Deferred tax liabilities	365,184	301,692
Other long-term liabilities	955,056	1,040,122
Total other long-term liabilities	1,420,852	1,341,814
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Common stock, par value $0.01, authorized 50,000,000 shares, issued and outstanding 27,649,887 in 2010 and 2009	276,498	276,498
Additional paid-in capital	41,389,404	41,204,712
Accumulated deficit	(31,686,472)	(27,471,793)
Accumulated other comprehensive loss	(612,860)	(283,732)
Total shareholders' equity	9,366,570	13,725,685
Total liabilities and shareholders' equity	$ 15,101,022	$ 19,132,394

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, 2010 and 2009

	2010	2009
NET REVENUE	$17,031,742	$18,401,925
COST OF SALES	8,212,678	8,299,575
Gross profit	8,819,064	10,102,350
OPERATING EXPENSES:		
Selling	4,901,855	5,584,439
General and administrative	6,450,807	6,674,493
Research and development	1,639,330	1,793,182
Impairment of product license	—	400,000
Total operating expenses	12,991,992	14,452,114
Loss from operations	(4,172,928)	(4,349,764)
OTHER INCOME, NET:		
Interest income	4,059	18,760
Other income, net	65,504	37,275
Total other income, net	69,563	56,035
Loss before income taxes	(4,103,365)	(4,293,729)
INCOME TAX PROVISION	111,314	164,131
Net loss	$(4,214,679)	$(4,457,860)
Loss per share		
Basic and diluted	$ (0.15)	$ (0.16)
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 Shareholder's Equity and Comprehensive Loss
For the Years Ended December 31, 2010 and 2009

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
	Shares	Amount				
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 loss						(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
Comprehensive loss:						
Net loss	—	—	—	(4,214,679)	—	(4,214,679)
Translation adjustment	—	—	—	—	(329,128)	(329,128)
Comprehensive loss						(4,543,807)
Stock compensation	—	—	184,692	—	—	184,692
BALANCE, December 31, 2010	27,649,887	$276,498	$41,389,404	$(31,686,472)	$(612,860)	$ 9,366,570

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, 2010 and 2009

	2010	2009
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss)	$(4,214,679)	$(4,457,860)
Adjustments to reconcile net loss to net cash used in operating activities –		
Depreciation and amortization	863,604	583,277
Provision (recovery) for doubtful accounts receivable	57,479	(5,516)
Reduction of provision for inventory obsolescence	(79,565)	—
Non-cash compensation	184,692	138,872
Deferred income tax provision	63,492	63,492
Impairment of product license	—	400,000
Changes in operating assets and liabilities:		
Accounts receivable	30,592	150,620
Inventories	749,217	(253,778)
Other current assets	150,696	(30,072)
Accounts payable and accrued expenses	315,813	65,879
Other long-term liabilities	(4,208)	110,702
Net cash used in operating activities	(1,882,867)	(3,234,384)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Capital expenditures	(256,886)	(199,095)
Acquisition of equipment on lease, net	(71,776)	(828,220)
Proceeds from sales of marketable securities	—	4,100,000
Increase in restricted deposits	(39,632)	(50,031)
Net cash provided by (used in) investing activities	(368,294)	3,022,654
CASH FLOWS FROM FINANCING ACTIVITIES:		
Capital lease payments	(49,819)	—
Net cash used in financing activities	(49,819)	—
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(71,705)	(10,257)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(2,372,685)	(221,987)
CASH AND CASH EQUIVALENTS, beginning of year	4,198,913	4,420,900
CASH AND CASH EQUIVALENTS, end of year	$ 1,826,228	$ 4,198,913
SUPPLEMENTAL DISCLOSURES:		
Income taxes paid	$ 52,481	$ 20,899
Interest paid	$ 24,171	$ —
Acquisition of equipment under capital lease	$ 222,000	$ —

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 these notes to consolidated financial statements, Debregeas & Associes Pharma SAS, Patrice R. Debregeas, Paul F. Kennedy and Umbria LLC are collectively known as the Debregeas-Kennedy Group.

On September 1, 2010, ERBA Diagnostics Mannheim GmbH, an in vitro diagnostics company headquartered in Germany ("ERBA"), the parent company of which is Transasia Bio-Medicals Ltd. ("Transasia"), purchased all of the approximately 72.4% of the outstanding shares of the Company's common stock owned by the Debregeas-Kennedy Group for an aggregate purchase price of approximately $15,000,000, or $0.75 per share (the "Share Acquisition"). As a result of the Share Acquisition, ERBA now beneficially owns, directly or indirectly, approximately 72.5% of the outstanding shares of the Company's common stock.

Upon the consummation of the Share Acquisition, two of the Company's executive officers — Charles R. Struby, Ph.D., the Company's Chief Executive Officer and President, and Steven E. Lufkin, the Company's General Manager, provided written notice to the Company of their resignation for "good reason" under their respective employment agreements in connection with the change in control caused by the Share Acquisition. As a result, the Company accrued severance benefits aggregating $475,000 in the third quarter of 2010 in general and administrative expenses, of which $355,000 remained to be paid at December 31, 2010 and is included in accrued expenses in the accompanying consolidated balance sheet.

2 GOING CONCERN

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, assuming the Company's ability to continue as a going concern. The Company has incurred a net loss of $4,214,679 during the year ended December 31, 2010 and used cash from operations of $1,882,867 during the year ended December 31, 2010.

In view of the matters described in the preceding paragraph, recoverability of a major portion of the recorded asset amounts shown in the accompanying consolidated balance sheet is dependent upon continued operations of the Company, which in turn is dependent upon the Company's ability to meet its operational cash flow demands on a continuing basis. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or amounts and classification of liabilities that might be necessary should the Company be unable to continue in existence.

The Company has taken or is in the process of evaluating or undertaking certain actions which, if successful, it believes will be sufficient to provide the Company with the ability to continue in existence. The Company expects operating results to improve from the operating results achieved during 2010 based principally upon increases in revenue as a result of the recent commercial launch of the Mago® 4S in the United States and increases in the United States and international revenue from new channels of distribution. The Company also expects operating results to improve as a result of certain initiatives it has adopted or is considering adopting in order to reduce expenses. The Company is also evaluating various forms of debt and equity financing arrangements. There can be no assurance that, if the Company seeks 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. Any such financing arrangements would likely impose positive and negative covenants, which could restrict various aspects of the Company's business, operations and finances. In addition, any issuance of equity securities, or securities convertible into shares of the Company's common stock, would be dilutive to the Company's existing stockholders. 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 be required to curtail or reduce its operations.

3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries Diamedix Corporation, ImmunoVision, Inc. and Delta Biologicals, S.r.l. All significant intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of consolidated financial statements in conformity with GAAP 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.

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

A significant portion of the Company's cash and cash equivalents are presently held in a money market fund at one international securities brokerage firm. Accordingly, the Company is subject to credit risk if this brokerage firm is unable to repay the balance in the account or deliver the Company's securities or if the brokerage firm should become bankrupt or otherwise insolvent. It is the Company's policy to invest only in select money market instruments, United States Treasury investments, municipal and other governmental agency securities and corporate issuers.

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 aggregate par value of $4,100,000. 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 generally 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 $399,376 and $356,162 at December 31, 2010 and 2009, respectively, and activity for the years then ended was as follows:

	2010	2009
Balance at January 1	$356,162	$358,268
(Recovery)/provision	57,479	(5,516)
Write-offs	—	(1,168)
Effects of changes in foreign exchange rates	(14,265)	4,578
Balance at December 31	$399,376	$356,162

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 United States Food and Drug Administration ("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,	
	2010	2009
Raw materials	$ 752,966	$ 707,054
Work-in-process	751,992	1,070,964
Finished goods	2,592,938	3,030,222
Total inventories, net	$4,077,896	$4,808,240

The Company regularly reviews inventory quantities on hand, which include components for current or future versions of products and instrumentation. If necessary, the Company records a provision for excess and obsolete inventory based primarily on its estimates of component obsolescence, product demand and production requirements, as well as based upon the status of a product within the regulatory approval process. In accordance with the Company's inventory accounting policy, the Company's inventory balance at December 31, 2010 included components for current or future versions of products and instrumentation. On September 30, 2009, the Company filed a 510(k) premarket submission with the FDA for the Mago® 4S, the Company's next-generation fully automated Enzyme-linked Immunosorbent Assay ("ELISA") and Immunofluorescence Assay ("IFA") system for autoimmune and infectious disease testing that the

Company intends to market in the United States. Regulatory approval was obtained in January 2011 and the Company expects to begin making commercial deliveries in the first quarter of 2011. The Company's inventory balance at December 31, 2010 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. Based upon amended regulatory standards adopted by the applicable notifying body during the fourth quarter of 2009 with which the Company must now comply in order to receive approval and additional requirements specified during 2010 by the applicable notifying body, the Company now expects "CE Marking" granting approval for the remaining products covered under the license agreement and product launch by the fourth quarter of 2011. At December 31, 2009, Mago® 4S instrumentation and instrument component inventories were approximately $260,000 and hepatitis related inventories were approximately $200,000.

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 was $582,885 and $397,235 during the years ended December 31, 2010 and 2009, 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 3, *Summary of Significant Accounting Policies*, under the heading of *Revenue Recognition*), less accumulated amortization, consists of the following:

	December 31,	
	2010	2009
Equipment on lease, at cost	$6,389,990	$6,219,021
Less accumulated amortization	5,710,552	5,367,221
	$ 679,438	$ 851,800

Equipment on lease is typically amortized over three or five years. Amortization expense was $280,719 and $186,042 for the years ended December 31, 2010 and 2009, respectively.

Long Lived Assets Including Goodwill

The components of the carrying amount of goodwill are as follows:

Balance as of January 1,	2010	2009
Goodwill	$ 6,722,725	$ 6,722,725
Accumulated impairment losses	(5,852,435)	(5,852,435)
Balance as of December 31,	$ 870,290	$ 870,290

As discussed in Note 4, *Impairment of Long-Lived Assets Including Goodwill*, the Company tests goodwill for possible impairment on an annual basis as of December 31 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 be recorded for these assets not previously recorded. There were no impairment charges to goodwill recorded during 2010 or 2009.

Product License

Through the acquisition of existing hepatitis technology under a perpetual, worldwide, royalty-free license, the Company expects to be able to derive revenue from the manufacture and sale of new hepatitis products following the completion of all of the performance objectives contained in the license agreement, which are required in order to complete the transfer of the technology to the Company. As discussed in Note 5, *Product License, Including Impairment Charge,* the Company tests its product license for possible impairment annually. 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. Fair value was determined based upon the income approach, which utilized significant assumptions to estimate fair value based upon future discounted cash flows. No impairment charges were recorded for the year ended December 31, 2010.

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 Company begins to 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 $228,680 and $200,995 as of December 31, 2010 and 2009, respectively, consist primarily of cash deposits required as part of the sales tender process with governmental customers in Italy.

Foreign Currencies

The Company has operations that are located in Italy and 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. Amounts in the consolidated statements of operations are translated at the average exchange rates for the period. 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.

The Company does not use financial derivatives to hedge exchange rate fluctuations.

Financial Instruments

The carrying amounts of cash and cash equivalents, marketable securities, accounts receivable, accounts payable and capital lease obligations 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, discounts and warranty claims. Provisions and discounts for the years ended December 31, 2010 and 2009 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.

The taxes that the Company has collected from its customers and remitted to governmental authorities are presented in the Company's consolidated statements of income on a net basis. Many of the Company's customers are tax exempt organizations.

Research and Development Costs

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

Other Income

In October 2010, the Company was awarded a cash grant of $244,479 under the Qualifying Therapeutic Discovery Projects Program (Section 48D of the Internal Revenue Code, which was enacted as part of the Patient Protection and Affordable Care Act of 2010). This grant was awarded in connection with therapeutic discovery projects relating to the Mago® 4S and certain diagnostic ELISA and IFA test kits. Pursuant to an arrangement between the Company and a third party consultant, which assisted the Company with respect to its application for the grant, the Company accrued payment to the consultant of 10% of the amount of the cash grant received by the Company, or $24,448. The net amount of $220,031 has been recorded in "Other income, net" in the consolidated statement of operations for the year ended December 31, 2010.

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. 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 United States Treasury yield curve in effect at the time of the 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, 2010 and 2009.

At December 31, 2010, the Company had stock-based employee compensation plans as described in Note 11, *Shareholders' Equity*. The Company recorded total compensation expense of $184,692 and $138,872 for the years ended December 31, 2010 and 2009, respectively.

Comprehensive Loss

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

	Year Ended December 31,	
	2010	2009
Net loss	$(4,214,679)	$(4,457,860)
Foreign currency translation adjustment	(329,128)	92,866
Comprehensive loss	$(4,543,807)	$(4,364,994)

Loss per Share

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

Outstanding stock options (1,248,198 as of December 31, 2010 and 1,130,116 as of December 31, 2009) have not been included in the calculation of loss per share because their impact would be anti-dilutive.

Recently Issued Accounting Standards

In July 2010, the Financial Accounting Standards Board ("FASB") issued disclosure requirements for companies to provide enhanced disclosures regarding the credit quality of their financing receivables and the credit reserves held against them. The main objective in developing the new disclosures is to provide users of the financial statements with greater transparency about a company's allowance for credit losses and the credit quality of its financing receivables. The new standards are intended to provide additional information to assist users of the financial statements in assessing a company's credit risk and evaluating the adequacy of any allowance for credit losses. The disclosures as of the end of a reporting period are effective for interim and annual reporting periods ending on or after December 31, 2010. This requirement did not have a material impact on the Company's disclosures. The disclosures about activities that occur during a reporting period are effective for interim and annual reporting periods beginning on or after December 15, 2010. The adoption of these new requirements is not expected to have a material impact on the Company's consolidated financial statements.

In April 2010, the FASB issued amended recognition and disclosure requirements regarding the milestone method of revenue recognition. The new guidance is designed to assist management in determining when it may be appropriate to apply the milestone method of revenue recognition for research or development transactions. The amendments affect companies that provide research or development deliverables in an arrangement in which one or more payments are contingent upon achieving uncertain future events or circumstances. The adoption of these new requirements is not expected to have a material impact on the Company's consolidated financial statements.

In February 2010, the FASB issued amended recognition and disclosure requirements regarding subsequent events. The new guidance is designed to clarify the interaction between promulgated FASB standards and the guidance from the Securities and Exchange Commission. This guidance became effective beginning with the quarter ended June 30, 2010. The adoption of these new requirements did not have a material impact on the Company's consolidated financial statements.

In January 2010, the FASB issued additional disclosure requirements for fair value measurements. According to the guidance, the fair value hierarchy disclosures are further disaggregated by class of assets and liabilities. A class is often a subset of assets or liabilities within a line item in the statement of financial position. In addition, significant transfers between Levels 1 and 2 of the fair value hierarchy are required to be disclosed. These additional requirements, which became effective January 1, 2010 for quarterly and annual reporting, did not have an impact on the Company's consolidated financial results, as this guidance related only to additional disclosures. In addition, the guidance requires more detailed disclosures of the changes in Level 3 instruments. These changes will be effective January 1, 2011 and are not expected to have a material impact on the Company's consolidated financial statements.

In October 2009, the FASB issued amended revenue recognition guidance for arrangements with multiple deliverables. The new guidance requires the use of management's best estimate of selling price (BESP) for the deliverables in an arrangement when vendor specific objective evidence (VSOE), vendor objective evidence (VOE) or third party evidence (TPE) of the selling price is not available. In addition, excluding specific software revenue guidance, the residual method of allocating arrangement consideration is no longer permitted, and an entity is required to allocate arrangement consideration using the relative selling price method. 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 implemented the new guidance effective January 1, 2011. The Company believes that the adoption of these new requirements will not have a material impact on the Company's consolidated financial statements.

In October 2009, the FASB also issued guidance which amended the scope of existing software revenue recognition guidance. Tangible products containing software components and non-software components that function together to deliver the tangible product's essential functionality is no longer within the scope of software revenue guidance and is accounted for based on other applicable revenue recognition guidance. In addition, the amendments exclude hardware components of a tangible product containing software components from the software revenue 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 implemented the new guidance effective January 1, 2011. The Company believes that the adoption of these new requirements will not have a material impact on the Company's consolidated financial statements.

4 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, 2010 and 2009, 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 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, rather than 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 fact 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 4 years, long-term annual growth rates of 10% to 12% and a discount rate of 25%, no impairment was noted in the year ended December 31, 2010.

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.

5 PRODUCT LICENSE, INCLUDING IMPAIRMENT CHARGE

In September 2004, the Company entered into a license agreement with an Italian diagnostics company to obtain a perpetual, worldwide, royalty-free license of product technology used by the Italian diagnostics company. This licensed hepatitis product technology is existing technology, which the Italian diagnostics company had developed and successfully commercialized to manufacture hepatitis products sold by them and for which it had already received "CE Marking" approval from the European Union. Through the acquisition of this existing technology in its current form, the Company expects to be able to derive revenue from the manufacture and sale of new hepatitis products. In exchange for the Italian diagnostics company's assistance in transferring the know-how of the manufacturing technology, the Company agreed to pay a total of 1,000,000 Euro in the form of four milestone payments upon the Italian diagnostics company's achievement of certain enumerated performance objectives related to the transfer of such existing technology. Three of the four milestone payments, totaling 900,000 Euro, were made in prior years. The remaining milestone payment of 100,000 Euro, or approximately $133,000, is included in accrued license payable in the accompanying

consolidated balance sheet as of December 31, 2010. Based upon amended regulatory standards adopted by the applicable notifying body during the fourth quarter of 2009 with which the Company must now comply in order to receive approval and additional requirements specified during 2010 by the applicable notifying body, the Company now expects "CE Marking" granting approval for the remaining products covered under the license agreement and product launch by the fourth 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 this methodology, and utilizing significant assumptions in the income approach that included a forecasted cash flow period of 5 years and revenue and gross margin estimates beginning in 2012, estimated future cash flows generated by the technology granted by the product license was calculated using a discount rate of 23%, 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.

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 Company begins to utilize the licensed technology for its intended purpose. Amortization of the product license will begin following the initial sale of the hepatitis products manufactured by the Company.

6 FAIR VALUE MEASUREMENT

In June 2009, the FASB issued new accounting standards that establish the FASB Accounting Standards Codification (the "ASC") as the official single source of authoritative GAAP and supersedes all previous accounting standards.

ASC Section 820, *Fair Value Measurements and Disclosures,* formerly Statement of Financial Accounting Standard ("SFAS") No. 157, 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. 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 ASC Section 820, all of the Company's financial assets, which do not include cash on hand, as of December 31, 2010 and December 31, 2009 were Level 1 assets composed of money market funds with balances of $993,916 and $2,943,522, respectively, and Level 3 assets composed of the product license discussed in Note 5, *Product License, Including Impairment Charge.*

7 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 to customers primarily in the United States and Italy. As of December 31, 2010 and 2009, $3,833,268 and $4,050,898, respectively, of total net accounts receivable were due in Italy. Of the consolidated net accounts receivable, approximately 39%, or $2,062,000, at December 31, 2010 and 38%, or $2,174,000, at

December 31, 2009 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 3, *Summary of Significant Accounting Policies*, under the heading *Accounts Receivable and Allowance for Doubtful Accounts*).

The Company's cash management and investment policies restrict investments to low-risk, highly liquid securities, and the Company performs periodic evaluations of the credit standing of the financial institutions with which it deals. However, as referenced in Note 3, *Summary of Significant Accounting Policies* under the heading *Marketable Securities*, a significant portion of the Company's cash and cash equivalents are presently held at one international securities brokerage firm. Accordingly, the Company is subject to credit risk if this brokerage firm is unable to repay the balance in the account or deliver the Company's securities or if the brokerage firm should become bankrupt or otherwise insolvent. These cash and cash equivalents are also in excess of federally insured limits.

8 INCOME TAXES

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

	Year Ended December 31,	
	2010	2009
Current:		
Domestic	$ —	$ —
Foreign	47,822	82,480
Deferred:		
Domestic	63,492	63,492
Foreign	—	18,159
Total	$111,314	$164,131

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

	Year Ended December 31,	
	2010	2009
Domestic	$(2,385,677)	$(2,946,877)
Foreign	(1,717,688)	(1,346,852)
Total	$(4,103,365)	$(4,293,729)

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

	December 31,	
	2010	2009
Current:		
Accounts receivable allowances	$ 127,360	$ 117,547
Reserves and accruals	400,217	308,191
Capitalized inventory costs	114,369	143,209
Valuation allowance	(641,946)	(568,947)
Deferred income taxes	—	—
Long-Term:		
Depreciation and basis differences on fixed and intangible assets	287,757	345,785
Stock based compensation	310,406	239,299
Other	(29,847)	(20,583)
Foreign net operating losses	1,718,537	1,560,585
Domestic net operating losses	5,620,434	4,649,982
Valuation allowance	(7,907,287)	(6,775,068)
Net deferred tax asset	$ —	$ —

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

	December 31,	
	2010	2009
Long-Term:		
Tax deductible goodwill	365,184	301,692
Net deferred tax liability	$365,184	$301,692

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. Accordingly, as of December 31, 2010 and 2009, the Company had no net domestic deferred tax assets. As of December 31, 2010 and 2009, the Company had net deferred tax liabilities of $365,184 and $301,692, respectively, relating to tax deductible goodwill which is not expected to reverse in the foreseeable future. Additionally, as of December 31, 2010 and 2009, the Company also had no net foreign deferred tax asset, as a full valuation allowance was provided. Future changes in the estimated net realizable value of the deferred tax assets or deferred tax liabilities could cause the provision for income taxes to vary significantly from period to period.

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,	
	2010	2009
Provision (benefit) for income taxes at U.S. Federal statutory rate of 35%	$(1,436,178)	$(1,502,805)
Change in valuation allowance (excluding portion relating to stock options)	1,163,342	1,083,032
Foreign tax rate differential	326,456	409,525
Global permanent differences	57,694	174,379
Provision (benefit) for income taxes	$ 111,314	$ 164,131

The Company's income tax provision or benefit for the years ended December 31, 2010 and 2009 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.

Domestic net operating losses generated by the Company total $14,411,000 and are subject to any applicable limitations as described below. The net operating losses included in the domestic net deferred tax asset will begin to expire in 2022. The net operating losses included in the foreign net deferred tax asset will begin to expire in 2011. 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 1, 2010 acquisition by ERBA of the approximately 72.4% of the outstanding shares of the Company's common stock previously owned by the Debregeas-Kennedy Group. 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 approximately $825,000 per year, plus

both any limitation unused since the acquisition and any unused net operating losses generated after the September 1, 2010 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, 2010 or 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, 2010, the Company's 2007-2010 federal tax returns and 2006-2010 Italian tax returns remain subject to examination. Although the Company's federal tax returns from 2001-2006 are not generally open to examination, the Company remains subject to adjustments in these years to the extent of the net operating losses being carried forward from these years. No examinations are currently in progress with any taxing authorities.

The Company implemented guidance relative to accounting for uncertainties in income taxes, effective at the beginning of the Company's fiscal year ended December 30, 2007. The Company recognizes the financial statement benefit of a tax position only after determining that the relevant tax authority would more likely than not sustain the position following an audit. For tax positions meeting the more-likely-than-not threshold, the amount recognized in the financial statements is the largest benefit that has a greater than 50% likelihood of being realized upon ultimate settlement with the relevant tax authority. At December 31, 2010 and 2009, 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.

9 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 $85,285 and $86,747 were made into this plan during the years ended December 31, 2010 and 2009, respectively.

10 ACCRUED EXPENSES AND OTHER LONG-TERM LIABILITIES

Accrued expenses consist of the following:

	December 31,	
	2010	2009
Payroll costs	$ 880,488	$ 794,135
Taxes, other than income taxes	1,191,439	1,250,892
Professional fees	11,200	215,822
Royalties	82,449	74,198
Other	346,122	360,586
	$2,511,698	$2,695,633

Other long-term liabilities consist of the following:

	December 31,	
	2010	2009
Italian employee leaving indemnity[1]	$922,346	$ 977,112
Other	32,710	63,010
	$955,056	$1,040,122

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

11 SHAREHOLDERS' EQUITY

Common Stock

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

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

Share Repurchase Program

During May 2002, the Company's Board of Directors approved a program to repurchase up to 1,000,000 shares of the Company's publicly held common stock. In December 2002, the Company's Board of Directors authorized an additional repurchase of up to 1,000,000 shares of the Company's publicly held common stock. During the years 2009 and 2010, 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

On June 3, 2009, the Company's stockholders approved the Company's 2009 Equity Incentive Plan (the "2009 Plan"), which the Company's Board of Directors had approved and recommended. 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 June 3, 2009, 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.

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, 2010 and changes during the years ended December 31, 2010 and 2009 under the Performance Plan and the 2009 Plan:

	Number of Shares	Weighted Average Exercise Price
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
Outstanding at December 31, 2009	1,130,116	$2.27
Granted	253,082	$0.55
Expired	(110,000)	$1.99
Terminated	(100,000)	$0.37
Exercised	—	—
Outstanding and exercisable at December 31, 2010	1,173,198	$2.09

Range of Exercise Prices	Options Outstanding			Options Exercisable	
	Number Outstanding	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.00–$0.50	150,000	8.3	$0.49	150,000	$0.49
$0.50–$0.75	403,082	8.5	$0.59	403,082	$0.59
$0.75–$1.00	100,000	6.6	$1.00	100,000	$1.00
$1.00–$1.50	100,000	7.7	$1.20	100,000	$1.20
$1.50–$3.00	100,000	5.7	$1.56	100,000	$1.56
$3.00–$6.00	150,000	4.5	$4.37	150,000	$4.37
$6.00–$9.00	170,116	0.4	$6.50	170,116	$6.50
	1,173,198	6.3	$2.09	1,173,198	$2.09

The aggregate intrinsic value of options outstanding and exercisable as of December 31, 2010 was $669,000. At December 31, 2010, all outstanding options were vested and therefore there was no unrecognized compensation cost. As of December 31, 2009, there were 100,000 unvested options with a weighted average grant date fair value of $0.46. No windfall tax benefits were recognized during the years ended December 31, 2010 or 2009.

12 SEGMENT INFORMATION

The Company's management reviews financial information, allocates resources and manages its business by geographic region. The domestic region, which includes corporate expenditures, contains the Company's subsidiaries in the United States. The 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, loss from operations, total assets and goodwill by region for the years ended December 31, 2010 and 2009:

	Domestic	European	Eliminations	Total
December 31, 2010:				
External net sales	$11,838,304	$ 5,193,438	$ —	$17,031,742
Intercompany sales	667,213	233,317	(900,530)	-
Net revenue	$12,505,517	$ 5,426,755	$(900,530)	$17,031,742
Loss from operations	$ (2,582,100)	$(1,590,828)	$ —	$ (4,172,928)
Assets	$ 8,479,223	$ 6,621,799	$ —	$15,101,022
Goodwill	$ 870,290	$ —	$ —	$ 870,290
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

13 COMMITMENTS AND CONTINGENCIES

Leases

Certain of the Company's office, plant and warehouse facilities are leased under non-cancelable operating leases. During the year ended December 31, 2010, the Company entered into operating leases with a financing company for certain diagnostic instruments that the Company placed as part of its reagent rental arrangements with customers. Diagnostic instrumentation acquired under these arrangements is placed at customer sites, and customers make reagent kit purchase commitments with the Company that typically last for a period of three to five years. The leases have terms of 30 months. At the end of the lease, the Company will have the option of purchasing the instrumentation from the financing company for an amount not to exceed 22% of the original price for which the financing company purchased such instrumentation. The future minimum lease payments under these and other non-cancelable operating leases with initial or remaining terms of one year or more at December 31, 2010 were as follows:

2011	$ 653,223
2012	555,624
2013	374,257
2014	83,214
2015	4,598
Total minimum lease payments	$1,670,916

Rent expense for the years ended December 31, 2010 and 2009 totaled $422,000 and $495,000, respectively.

During the year ended December 31, 2010, the Company entered into a 36-month capital lease agreement with the same financing company for bottling equipment for its production facility in Miami, Florida. The terms of the lease require that the Company make equal monthly payments and grant the Company the option to purchase the equipment at the end of the lease for an amount not to exceed 22% of the original price for which the financing company purchased such equipment. The asset and liability under this capital lease are recorded at the lower of the present value of the minimum lease payments or the fair value of the asset. The asset is depreciated over its estimated productive life. Depreciation of $16,669 in 2010 was included in cost of sales. The following table contains summary information regarding property held under this capital lease as of December 31, 2010:

Production equipment	$222,257
Accumulated depreciation	(16,669)
	$205,588

Future minimum lease payments under this capital lease as of December 31, 2010 are as follows:

2011	$ 84,360
2012	84,360
2013	14,060
Total remaining minimum lease payments required	182,780
Less amount representing interest	(10,342)
Net present value of minimum lease payments	$172,438

The net present value of minimum lease payments is reflected in the accompanying consolidated balance sheet as of December 31, 2010 as current and long-term capital lease obligations of $71,826 and $100,612, respectively. The interest rate used on the capitalized lease is the Company's incremental borrowing rate. Interest expense during the year ended December 31, 2010 was $13,454.

Litigation, Claims and Assessments

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

14 QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following table summarizes selected quarterly data for the years ended December 31, 2010 and 2009 (in thousands except per share data):

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter[1][2]	Full Year
2010					
Net revenue	$4,652	$ 4,394	$ 3,952	$ 4,034	$17,032
Gross profit	2,488	2,335	2,131	1,865	8,819
Loss from operations	(881)	(1,246)	(1,123)	(923)	(4,173)
Net loss	(958)	(1,311)	(1,176)	(770)	(4,215)
Basic and diluted loss per share	(0.03)	(0.05)	(0.04)	(0.03)	(0.15)
2009					
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 loss per share	(0.02)	(0.05)	(0.04)	(0.05)	(0.16)

(1) The net loss for the fourth quarter of 2010 includes net grant proceeds of $220, as discussed in Note 3, *Summary of Significant Accounting Policies*, under the heading of *Other Income*.

(2) The loss from operations for the fourth quarter of 2009 includes the effect of the write-off of $400, a portion of the value of the Company's product license of hepatitis technology, as discussed in Note 5, *Product License, Including Impairment Charge*.

Basic and diluted 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 loss per share amounts due to the effects of rounding.

15 RELATED PARTY TRANSACTIONS

During the year ended December 31, 2010, the Company paid $119,000 to Lawrence G. Meyer in consideration for his provision of certain legal services which he provided to the Company on an as-needed basis. Mr. Meyer served on the Company's Board of Directors until his resignation from the Board of Directors on September 1, 2010. During the year ended December 31, 2010, ImmunoVision paid $42,000 to John B. Harley, M.D., Ph.D., under that certain oral consulting agreement between Dr. Harley and ImmunoVision, pursuant to which Dr. Harley was paid $5,000 per month from January 2010 through June 2010 and $2,000 per month from July 2010 through December 2010, in consideration for his provision of technical guidance and business assistance to ImmunoVision on an as-needed basis. Dr. Harley continues to serve on the Company's Board of Directors. The amounts paid to Mr. Meyer and Dr. Harley, in each case as described above, were in addition to the amounts they received for their service as members of the Company's Board of Directors and the committees of the Board of Directors on which they served.

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

Previously reported.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of the end of the period covered by this Annual Report on Form 10-K, 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, 2010.

Pursuant to the 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 the 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, 2010 that 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 25, 2011.

Name	Age	Position
Kevin D. Clark	48	Chief Executive Officer, Chief Operating Officer and President
Arthur R. Levine	53	Chief Financial Officer and Vice President — Finance
Suresh Vazirani	61	Executive Chairman of the Board of Directors
Kishore "Kris" Dudani	56	Director
Philippe Gadal, Pharm.D.	54	Director
John B. Harley, M.D., Ph.D.	61	Director
David M. Templeton	58	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 25, 2011. 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.

Kevin D. Clark, age 48, was named our President and Chief Executive Officer on September 3, 2010. He 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.

Arthur R. Levine, age 53, was appointed our Chief Financial Officer in August 2010 and our Vice President — Finance in April 2010. Prior to joining us, Mr. Levine was employed by Airspan Networks Inc., a publicly traded vendor of wireless products and solutions, where he served as Vice President — Finance and Controller from January 2006 through September 2009 after previously serving as Director of Finance beginning in October 2005. From 2003 through 2005, Mr. Levine served as Director of Finance of DentaQuest Ventures, Inc., a privately-held third party administrator and insurer of dental benefits. From 1995 through 2003, Mr. Levine was employed by Scitex Corporation Ltd., a publicly traded manufacturer of digital printing equipment, where he served in a number of financial roles, including Vice President and Corporate Controller. Mr. Levine worked at Ernst & Young LLP from 1984 through 1995. He received a B.S. from the Wharton School of the University of Pennsylvania and is a Certified Public Accountant.

Suresh Vazirani, age 61, was appointed to our Board of Directors and named Executive Chairman of the Board of Directors on September 1, 2010. Mr. Vazirani has served as the Chief Executive Officer of ERBA, an in vitro diagnostics company headquartered in Germany, since 2002 and the Chairman and Managing Director of Transasia Bio-Medicals Ltd., a diversified research and development based, export oriented in vitro diagnostics company headquartered in India and the parent company of ERBA, since 1985. As described above, ERBA beneficially owns, directly or indirectly, approximately 72.5% of the outstanding shares of our common stock. With over 25 years of experience in leading companies belonging to the in vitro diagnostics industry, the Board of Directors believes that Mr. Vazirani brings strategic insight and leadership and a wealth of knowledge regarding the diagnostics industry to the Board of Directors. The Board of Directors also believes that Mr. Vazirani's experience in, and knowledge of, the international in vitro diagnostics market contributes greatly to the composition of the Board of Directors and provides a valuable resource to us. Mr. Vazirani is the first cousin of Kishore "Kris" Dudani.

Kishore "Kris" Dudani, age 56, was appointed to the Board of Directors on September 1, 2010. Since 2004, Mr. Dudani has served as the Marketing and Business Development Representative — South, Central and Latin America, of ERBA. The Board of Directors believes that Mr. Dudani's background in the in vitro diagnostics industry allows him to contribute valuable insight to the Board of Directors and that his insights and experience in the field of international marketing of in vitro diagnostic products will be valuable in helping to guide us in the years ahead. Mr. Dudani is the first cousin of Suresh Vazirani.

Dr. Philippe Gadal, age 54, was appointed to the Board of Directors on September 1, 2010. Since 2009, Dr. Gadal has served as the Chief Executive Officer of AES Chemunex Inc., a manufacturer and developer of tests, equipment and reagents for microbiological laboratories. From 2003 through 2008, he served as the Chief Executive Officer of Trinity Biotech USA Inc., the United States subsidiary of Trinity Biotech PLC, an international diagnostics company which specializes in the development, manufacture and marketing of diagnostic test kits. Prior to joining Trinity Biotech, Dr. Gadal served in a variety of positions for companies involved in the in vitro diagnostics industry, including: General Manager of Diagnostica Stago Inc., a private medical devices company, from 1995 through 2003; Director of Hematology for Roche Diagnostics, a subsidiary of Hoffmann-La Roche Ltd., a leading company in the field of pharmaceutical and diagnostics, from 1993 through 1995; Director of the Hematology Business Unit for ABX France, a subsidiary of Hoffman-La Roche, from 1991 through 1992; President of ABX USA, a medical devices company that specializes in hematology, from 1988 through 1990; and Sales Representative for—and subsequently National Sales Manager of—Technicon, an international medical devices company, from 1984 through 1988. He received a Doctorate of Pharmacy (Pharm.D.) from Paul Sabatier University in France. The Board of Directors believes that Dr. Gadal's vast experience as an executive officer of companies within the life sciences industry and his international background provides him with the ability to contribute valuable insight to the Board of Directors with respect to our business and technologies.

Dr. John B. Harley, age 61, has served as a director on our Board of Directors since our merger with the pre-merger IVAX Diagnostics in 2001. Since June 2010, Dr. Harley has served as Director, Rheumatology Division, and Director, Center for Autoimmune Genomics and Etiology (CAGE), for Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio and is Professor of Pediatrics and Medicine, Affiliated, at the University of Cincinnati. He previously held various positions at the University of Oklahoma Health Sciences Center beginning in 1982. In the Department of Medicine, his positions included Chief of Rheumatology, Allergy and Immunology Section (1999 to 2010), 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 2010), Associate Professor (1986 to 1992) and Assistant Professor (1982 to 1986). During that period, Dr. Harley also held Adjunct Professorships in Pathology and Microbiology at the University of Oklahoma Health Sciences Center. Since 1982, Dr. Harley was also associated with the Oklahoma Medical Research Foundation's Arthritis and Immunology Program as Program Head (1999 to 2010), Member (1998 to 2010), Associate Member (1989 to 1998), Affiliated Associate Member (1986 to 1989) and Affiliated Assistant Member (1982 to 1986). Dr. Harley also served as a Staff Physician (1982, 1984 to 1987 and 1992 to 2010) and a Clinical Investigator (1987 to 1992), Immunology Section, Medical Service at the Veterans Affairs Medical Center, Oklahoma City, Oklahoma, and since July 2010, at the Veterans Affairs Medical Center, Cincinnati, Ohio. 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., a corporation of which Dr. Harley is the controlling shareholder, or JK Autoimmunity, 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 the 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, the 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 of Directors.

David M. Templeton, age 58, was appointed to the Board of Directors on September 15, 2010, and his service on the Board of Directors became effective on September 30, 2010. Mr. Templeton has served as the President and Chief Operating Officer of Global Vetnostics Incorporated, a veterinary reference laboratory, since 2006

and the Chief Operating Officer of Cataehem Inc., a manufacturer of human and veterinary clinical chemistry reagents, since July 2010. Mr. Templeton has also served as a business development consultant for Advy Chemical, a manufacturer of raw materials for use in the in vitro diagnostics industry, since 2005. Prior to that time, Mr. Templeton co-founded, and from 1983 until 2003 served as the Chief Executive Officer of Diagnostic Chemicals Limited USA, a developer and manufacturer of diagnostic reagents, test kits and point of care diagnostic devices which was eventually acquired by Genzyme Corporation, the company with which Mr. Templeton began his career. The Board of Directors believes that Mr. Templeton provides constructive insight to the Board of Directors as a result of his extensive background in the life sciences and diagnostics industries and that such background further strengthens the Board's composition.

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 NYSE Amex. 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, 2010.

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 NYSE Amex.

Audit Committee Members and Financial Expert

The members of the Audit Committee of our Board of Directors are Philippe Gadal, Pharm.D., and David M. Templeton. Our Board of Directors has determined that each of Dr. Gadal and Mr. Templeton 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 Dr. Gadal and Mr. Templeton is "independent," as such term is defined in the applicable regulations of the Securities and Exchange Commission and rules of the NYSE Amex relating to directors serving on audit committees.

ITEM 11. EXECUTIVE COMPENSATION

Compensation of Named Executive Officers

Summary Compensation Table—2010

The following table sets forth certain summary information concerning compensation which, during the fiscal years ended December 31, 2010 and 2009, we paid or accrued to or on behalf of (i) each individual serving or acting as our principal executive officer during the fiscal year ended December 31, 2010, (ii) the only other individual (other than our current principal executive officer) serving as an executive officer at December 31, 2010, and (iii) two additional individuals who, but for the fact that such individuals were not serving as executive officers at December 31, 2010, would have also been included under clause (ii) above (collectively, the "Named Executive Officers").

Name and Principal Position	Year	Salary	Bonus	Stock Awards	Option Awards[6]	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation[7]	Total
Kevin D. Clark,[1]									
Chief Executive Officer	2010	$227,000	—	—	—	—	—	—	$227,000
	2009	$227,000	—	—	—	—	—	$ 35,796	$262,796
Charles R. Struby, Ph.D.,[2]									
Former Chief Executive Officer	2010	$234,214	—	—	—	—	—	$281,136	$515,350
	2009	$234,932	$25,000	—	$30,000	—	—	—	$289,932
Arthur R. Levine,[3]									
Chief Financial Officer	2010	$108,575	—	—	$32,500	—	—	—	$141,075
	2009	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Mark S. Deutsch,[4]									
Former Chief Financial Officer	2010	$ 84,321	—	—	$56,935	—	—	$159,075	$300,331
	2009	$159,075	—	—	—	—	—	$ 21,108	$180,183
Steve E. Lufkin,[5]									
Former General Manager	2010	$184,017	$15,000	—	$36,660	—	—	$225,000	$460,677
	2009	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

(1) Mr. Clark was appointed as our Chief Executive Officer and President on September 3, 2010. Throughout the fiscal years ended December 31, 2009 and 2010, Mr. Clark served as, and Mr. Clark continues to serve as, our Chief Operating Officer and the Chief Operating Officer of ImmunoVision. On March 27, 2009, Mr. Clark entered into an employment agreement with us, which was amended on August 31, 2010 and on September 3, 2010. The terms of Mr. Clark's employment agreement and the amendments thereto are described under "Potential Payments upon Termination or Change-in-Control" below.

(2) Dr. Struby served as our Chief Executive Officer and President from January 23, 2009 until his resignation from such positions on September 3, 2010. Dr. Struby was employed by us pursuant to the terms of the employment agreement we entered into with him on March 27, 2009. In connection with his resignation as our Chief Executive Officer and President, we and Dr. Struby entered into a confidential general release of all claims on December 20, 2010, pursuant to which, among other things, we agreed to pay Dr. Struby $205,000 in lieu of any compensation that he would otherwise have been entitled to receive in accordance with his employment agreement. The payment contemplated by the confidential general release of all claims is required to be made in two equal installments, the first of which was paid on or before January 5, 2011 and the second of which is due on or before March 31, 2011. The terms of Dr. Struby's employment agreement, which has now been terminated, and his confidential general release of all claims with us are described in further detail under "Potential Payments upon Termination or Change-in-Control" below.

(3) Mr. Levine was appointed as our Chief Financial Officer effective September 1, 2010 and joined our company as Vice President — Finance on April 5, 2010. Prior to April 5, 2010, Mr. Levine was not employed by us and, accordingly, he did not receive any compensation from us during the year ended December 31, 2009 or prior to April 5, 2010 during the year ended December 31, 2010. On April 5, 2010, Mr. Levine entered into an employment agreement with us, which was amended on September 1, 2010. The terms of Mr. Levine's employment agreement and the amendment thereto are described under "Potential Payments upon Termination or Change-in-Control" below.

(4) Mr. Deutsch served as our Chief Financial Officer until his resignation from such positions on May 21, 2010. In connection with his resignation as our Chief Financial Officer, we and Mr. Deutsch entered into a separation letter agreement on May 3, 2010, pursuant to which, among other things, we agreed to pay Mr. Deutsch an amount equal to his then current annual base salary. This separation payment was paid in regular bi-weekly installments until September 22, 2010, at which time the remaining amount of the separation payment was paid to Mr. Deutsch in one lump sum payment. The terms of Mr. Deutsch's separation letter agreement with us are described in further detail under "Potential Payments upon Termination or Change-in-Control" below.

(5) Mr. Lufkin served as our General Manager from January 4, 2010 until his resignation on September 30, 2010. Prior to January 4, 2010, Mr. Lufkin was not employed by us and, accordingly, he did not receive any compensation from us during the year ended December 31, 2009 or prior to January 4, 2010 during the year ended December 31, 2010. Mr. Lufkin was employed by us pursuant to the terms of the employment agreement we entered into with him on January 4, 2010. In connection with his resignation as our General Manager, we and Mr. Lufkin entered into a confidential general release of all claims on September 30, 2010, pursuant to which, among other things, we agreed to pay Mr. Lufkin a one time lump sum payment of $225,000. The terms of Mr. Lufkin's employment agreement, which has now been terminated, and his confidential general release of all claims with us are described in further detail under "Potential Payments upon Termination or Change-in-Control" below.

(6) 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 11 to our Consolidated Financial Statements, *Shareholders' Equity*. The amount for Mr. Deutsch in 2010 represents the incremental fair value, computed as of the modification date in accordance with Codification Topic 718, *Compensation — Stock Compensation*, attributable to the modification of the options to purchase shares of our common stock previously granted to Mr. Deutsch, which options were modified pursuant to his separation letter agreement to remain in full force and effect until the earlier of their exercise in full or their respective expiration dates, notwithstanding any contrary provisions contained in our equity incentive plans pursuant to which such options were granted or agreements between us and Mr. Deutsch with respect to such options.

(7) The 2010 items under "All Other Compensation" for the applicable Named Executive Officers are as follows: Dr. Struby — $205,000 of separation payments, $60,210 of expense reimbursement associated with his relocation, and $15,926 of tax reimbursements; Mr. Deutsch — $159,075 of separation payments; and Mr. Lufkin — $225,000 of separation payments. Additional information about the separation payments to Dr. Struby and Messrs. Deutsch and Lufkin is set forth under "Potential Payments upon Termination or Change-in-Control" below.

Outstanding Equity Awards at Fiscal Year-End — 2010

The following table sets forth certain information regarding equity based awards held by the Named Executive Officers as of December 31, 2010.

	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
Kevin D. Clark	50,000	—	—	$0.65	9/22/18
	50,000	—	—	$1.20	9/22/18
Charles R. Struby, Ph.D.	—	—	—	—	—
Arthur R. Levine	50,000	—	—	$0.65	4/4/20
Mark S. Deutsch	5,116[1]	—	—	$7.12	3/17/11
	10,000	—	—	$4.35	7/13/15
	50,000	—	—	$0.65	9/22/18
	50,000	—	—	$1.20	9/22/18
Steven E. Lufkin	—	—	—	—	—

(1) These options expired on March 17, 2011, but they are included because they had not yet expired as of December 31, 2010.

Potential Payments upon Termination or Change-in-Control

Employment Agreement with Kevin D. Clark. On March 27, 2009, we entered into an employment agreement with Kevin D. Clark to serve as 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 during 2010. 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 annual 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.

Amendments to Employment Agreement with Kevin D. Clark. On August 31, 2010, Mr. Clark's employment agreement was amended to waive his right (i) to terminate his employment for "Good Reason" in connection with ERBA's acquisition of the shares of our common stock from the Debregeas-Kennedy Group and (ii) to receive the above-described severance compensation in connection therewith. Additionally, effective September 3, 2010, Mr. Clark was appointed to serve as our Chief Executive Officer and President and his employment agreement was amended solely to reflect his new positions without any other alterations to the terms and conditions, including the compensation terms, of his employment. Mr. Clark also continues to serve as our Chief Operating Officer.

Employment Agreement with Charles R. Struby, Ph.D. On March 27, 2009, we entered into an employment agreement with Charles R. Struby, Ph.D., who then served as our Chief Executive Officer and President. Dr. Struby's employment agreement had an initial term of three years and provided for automatic successive one year renewal periods unless either Dr. Struby or we exercised the option to allow the employment agreement to expire at the end of the then-current term. Under the employment agreement, Dr. Struby received an annual base salary of $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 were scheduled to expire on March 26, 2019. (As described below, Dr. Struby forfeited all of these options, effective December 20, 2010.) The employment agreement also provided that Dr. Struby would 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 during 2010. In addition, under the employment agreement, we were required to reimburse Dr. Struby for certain relocation and business expenses. The employment agreement also provided that, (i) 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 would be entitled to receive all base salary compensation which had been fully earned but had not yet been paid to him, and all of Dr. Struby's unvested equity-based awards would be forfeited, (ii) 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 would be entitled to receive or be reimbursed for, as the case may be, all base salary and annual cash bonus compensation which had been fully earned but had not yet been paid to him and all relocation and business expenses incurred by him which had not yet been reimbursed (such compensation, collectively, the "Struby Accrued Compensation"), and (iii) 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, would 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. The employment agreement further provided that, in the event we terminated the employment agreement without "Cause," the employment agreement was terminated as a result of Dr. Struby's "Disability" or Dr. Struby resigned 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, would 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, would 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 became covered by another employer group health plan or by Medicare. The employment agreement also included non-disclosure, non-solicitation, anti-raiding and non-disparagement covenants by Dr. Struby.

Confidential General Release of All Claims with Charles R. Struby, Ph.D. In connection with Dr. Struby's resignation as our Chief Executive Officer and President on September 3, 2010, we and Dr. Struby entered into a confidential general release of all claims on December 20, 2010, pursuant to which, among other things, we agreed to pay Dr. Struby $205,000 in lieu of any compensation that he would otherwise have been entitled to receive in accordance with his employment agreement. The payment contemplated by the confidential general release of all claims is required to be made in two equal installments, the first of which was paid on or before January 5, 2011 and the second of which is due on or before March 31, 2011. We also agreed, as had been contemplated by Dr. Struby's employment agreement, to 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 in which Dr. Struby or his spouse or dependents were participating at September 3, 2010 and to continue Dr. Struby's and his spouse's and dependents' medical coverage for a period ending upon the earlier of September 3, 2011 and such time as Dr. Struby becomes covered by another employer group health plan or by Medicare. Under the terms of the confidential general release of all claims, Dr. Struby provided a general release in favor of us, and he forfeited in its entirety the option to purchase 100,000 shares of our common stock which was previously granted to him under our 1999 Performance Equity Plan. The confidential general release of all claims also contains a mutual non-disparagement covenant by and between us and Dr. Struby, and an acknowledgement by Dr. Struby that he continues to be bound by non-disclosure, non-solicitation and anti-raiding covenants contained in his employment agreement with us.

Employment Agreement with Arthur R. Levine. On April 5, 2010, we entered into an employment agreement with Arthur R. Levine to serve as our Vice President — Finance. Mr. Levine's employment agreement does not have a stated term. Under the employment agreement, Mr. Levine was paid an initial annual base salary of $135,000, and we will review Mr. Levine's base salary at least annually. Mr. Levine's current annual base salary was increased to $170,000 effective September 1, 2010 in connection with his promotion to Chief Financial Officer. In addition, under the terms and conditions of the employment agreement, Mr. Levine received options to purchase 50,000 shares of our common stock under our 2009 Equity Incentive Plan at an exercise price of $0.65 per share, which equaled the closing price of our common stock on the NYSE Amex on April 5, 2010. These options fully vested as of April 5, 2010 and will expire on April 4, 2020. The employment agreement also provides that Mr. Levine 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. Mr. Levine did not receive an annual cash bonus during 2010. In addition, under the employment agreement, we are required to reimburse Mr. Levine for business expenses in accordance with our policies and procedures for expense reimbursement. Upon the termination of the employment agreement by us without "Cause" (as defined in the employment agreement) or upon Mr. Levine's resignation for "Good Reason" (as defined in the employment agreement), Mr. Levine will be entitled to receive 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 have not yet been reimbursed and a one-time lump sum payment in an amount equal to fifty percent (50%) of Mr. Levine's annual base salary in effect as of the effective date of termination, and we, at our sole expense, would maintain in full force and effect for a period of six months for the continued benefit of Mr. Levine 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 Mr. Levine or his spouse or dependents were participating. The employment agreement also includes non-disclosure, non-solicitation, anti-raiding and non-disparagement covenants by Mr. Levine.

Amendment to Employment Agreement with Arthur R. Levine. On September 1, 2010, Mr. Levine's employment agreement was amended to reflect that Mr. Levine was appointed to serve as our Chief Financial Officer, that he would report directly to the Chairman of the Board of Directors and that his annual base salary was increased to $170,000. Mr. Levine also continues to serve as our Vice President — Finance.

Letter Agreement with Mark S. Deutsch. On May 3, 2010, we and Mr. Deutsch, our then-serving Chief Financial Officer, entered into a letter agreement pursuant to which Mr. Deutsch's employment with us ceased, effective May 21, 2010. Under the terms and conditions of the letter agreement, we agreed to pay Mr. Deutsch a separation payment in an amount equal to his then-current annual base salary. This separation payment was be paid in regular bi-weekly installments until September 22, 2010, at which time the remaining amount of the separation payment was paid to Mr. Deutsch in one lump-sum payment. The letter agreement further provided that all options to purchase shares of our common stock previously granted to, and then held by, Mr. Deutsch will remain in full force and effect until the earlier of their exercise in full or their respective expiration dates, notwithstanding any contrary provisions contained in our equity incentive plans pursuant to which such options were granted or agreements between us and Mr. Deutsch with respect to such options. In addition, we agreed to pay for Mr. Deutsch's health insurance under COBRA until May 21, 2011. The letter agreement also includes a release by Mr. Deutsch in favor of us, as well as a non-disparagement covenant by Mr. Deutsch.

Employment Agreement with Steven E. Lufkin. On January 4, 2010, we entered into an employment agreement with Steven E. Lufkin, who then served as our General Manager. Mr. Lufkin's employment agreement had an initial term of two years and provided for automatic successive one year renewal periods unless either Mr. Lufkin or we exercised the option to allow the employment agreement to expire at the end of the then-current term. Under the employment agreement, Mr. Lufkin received a signing bonus of $15,000 and an annual base salary of $225,000, and he was eligible to receive, among other things, an annual cash bonus of up to 50% of his base salary 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. Mr. Lufkin did not receive an annual cash bonus during 2010. In addition, under the employment agreement, we were required to reimburse Mr. Lufkin for certain relocation and business expenses. The employment agreement also provided that, (i) upon the termination of the employment agreement by us with "Cause" (as defined in the employment agreement) or upon Mr. Lufkin's resignation other than for "Good Reason" (as defined in the employment agreement), Mr. Lufkin would be entitled to receive all base salary compensation which had been fully earned but had not yet been paid to him, and all of Mr. Lufkin's unvested equity-based awards would be forfeited, (ii) upon the expiration of the employment agreement as a result of either our or Mr. Lufkin's election to allow the employment agreement to expire at the end of the then-current term, Mr. Lufkin would be entitled to receive or be reimbursed for, as the case may be, all base salary and annual cash bonus compensation which had been fully earned but had not yet been paid to him and all relocation and business expenses incurred by him which had not yet been reimbursed (such compensation, collectively, the "Lufkin Accrued Compensation"), and (iii) upon the termination of the employment agreement by us without "Cause" or as a result of Mr. Lufkin's "Disability" (as defined in the employment agreement) or death, or upon Mr. Lufkin'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 two-year term of the employment agreement, Mr. Lufkin or his estate, as the case may be, would be entitled to receive the Lufkin Accrued Compensation and a one-time lump sum payment in an amount equal to Mr. Lufkin's then-current base salary. The employment agreement further provided that, in the event we terminated the employment agreement without "Cause," the employment agreement was terminated as a result of Mr. Lufkin's "Disability" or Mr. Lufkin resigned for "Good Reason," including, without limitation, as a result of a "Change in Control" during the initial two-year term of the employment agreement, we, at our sole expense, would maintain in full force and effect for a period of twelve months for the continued benefit of Mr. Lufkin 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 Mr. Lufkin or his spouse or dependents were participating, and we, at our sole expense, would continue Mr. Lufkin'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. Lufkin became covered by another employer group health plan or by Medicare. The employment agreement also included non-disclosure, non-solicitation, anti-raiding and non-disparagement covenants by Mr. Lufkin.

Confidential General Release of All Claims with Steven E. Lufkin. In connection with Mr. Lufkin's resignation as our General Manager on September 30, 2010, we and Mr. Lufkin entered into a confidential general release of all claims on September 30, 2010, pursuant to which, among other things, we agreed to pay Mr. Lufkin a one-time lump-sum payment of $225,000. We also agreed, as had been contemplated by Mr. Lufkin's employment agreement, to maintain in full force and effect for a period of twelve months for the continued benefit of Mr. Lufkin and his spouse and dependents all welfare benefit plans and programs in which Mr. Lufkin or his

spouse or dependents were participating at September 30, 2010 and to continue Mr. Lufkin's and his spouse's and dependents' medical coverage for a period ending upon the earlier of September 30, 2011 and such time as Mr. Lufkin becomes covered by another employer group health plan or by Medicare. Under the terms of the confidential general release of all claims, Mr. Lufkin provided a general release in favor of us. The confidential general release of all claims also contains an acknowledgement by Mr. Lufkin that he continues to be bound by non-disclosure, non-solicitation and anti-raiding covenants contained in his employment agreement with us.

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 10, 2010, (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 $0.53 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.

On November 10, 2010, the Compensation Committee recommended, and the Board of Directors approved, a change to our practice of compensating directors who are deemed to be "independent" under the NYSE Amex rules relating to the independence of directors for his services on the Board of Directors, Audit Committee and Compensation Committee, such that the options granted will terminate (to the extent not previously exercised or terminated) one month after such time, if any, as the applicable director's service on the Board of Directors ceases. After their appointment to the Board of Directors, on November 10, 2010, each of Philippe Gadal, Pharm.D., and David M. Templeton was paid and granted compensation for his services on the Board of Directors, Audit Committee and Compensation Committee in accordance with our then current practices as described in further detail above and after giving effect to the change in practice also described above.

Prior to 2009, 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, IVAX Corporation, 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, a change to this practice pursuant to which non-employee directors who were not "independent" under applicable NYSE Amex rules would be eligible to receive compensation for their service on the Board. Consistent with this change in practice and the related director compensation granted during 2009, on June 10, 2010 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 employed by us, for their service on the Board, notwithstanding the fact that neither Mr. Debregeas nor Mr. Kennedy was an "independent" director under the NYSE Amex rules relating to the independence of directors.

Upon their appointment on September 1, 2010, Suresh Vazirani and Kishore "Kris" Dudani stated that, as employees of ERBA, they would not require any compensation for their service on the Board of Directors, Audit Committee or Compensation Committee. As a result, on September 1, 2010, the Compensation Committee recommended, and the Board of Directors approved, a change to our practice of compensating directors who were not deemed to be "independent" under the NYSE Amex rules relating to the independence of directors, such that directors who were not deemed to be "independent" under the NYSE Amex rules relating to the independence of directors, including directors who are employed by us or ERBA, will not receive any compensation for their service on the Board of Directors, Audit Committee or Compensation Committee.

Director Compensation — 2010

The following table sets forth certain information regarding the compensation paid to our directors for their service during the fiscal year ended December 31, 2010.

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards[5]	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Suresh Vazirani[1]	—	—	—	—	—	—	—
Kishore "Kris" Dudani[1]	—	—	—	—	—	—	—
Philippe Gadal, Pharm.D.[1]	$10,833	—	$ 7,519	—	—	—	$ 18,352
John B. Harley, M.D., Ph.D.	$25,000	—	$12,933	—	—	$ 42,000[6]	$ 79,933
David M. Templeton[2]	$ 8,125	—	$ 7,519	—	—	—	$ 15,644
Jerry C. Benjamin[3]	$20,625	—	$12,933	—	—	—	$ 33,558
Patrice R. Debregeas[4]	$15,000	—	—	—	—	—	$ 15,000
Paul F. Kennedy[4]	$15,000	—	—	—	—	—	$ 15,000
Laurent Le Portz[3]	$24,375	—	$12,933	—	—	—	$ 37,308
Lawrence G. Meyer[4]	$18,750	—	$12,933	—	—	$119,000[7]	$150,683

(1) Each of Messrs. Vazirani and Dudani and Dr. Gadal was appointed to the Board of Directors on September 1, 2010.

(2) Mr. Templeton's appointment to the Board of Directors became effective on September 30, 2010.

(3) Each of Messrs. Benjamin and LePortz served on the Board of Directors until his resignation from the Board of Directors on September 30, 2010.

(4) Each of Messrs. Debregeas, Kennedy and Meyer served on the Board of Directors until his resignation from the Board of Directors on September 1, 2010.

(5) 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 11 to our Consolidated Financial Statements, *Shareholders' Equity*. The table below sets forth, as of December 31, 2010, the aggregate number of stock options held by each of the individuals included in the table above:

Name	Stock Options
Suresh Vazirani	—
Kishore "Kris" Dudani	—
Philippe Gadal, Pharm.D.	14,041
John B. Harley, M.D., Ph.D.	165,000
David M. Templeton	14,041
Jerry C. Benjamin	75,000
Patrice R. Debregeas	—
Paul F. Kennedy	—
Laurent Le Portz	75,000
Lawrence G. Meyer	75,000

(6) Represents the aggregate dollar amount earned by Dr. Harley during 2010 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, $5,000 per month from August 2009 to June 2010, and $2,000 per month thereafter, to provide ImmunoVision with technical guidance and business assistance on an as-needed basis.

(7) Represents the aggregate dollar amount earned by Mr. Meyer during 2010 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 25, 2011, information about the beneficial ownership of our common stock by (i) each director as of March 25, 2011, (ii) each Named Executive Officer, (iii) all directors and executive officers as of March 25, 2011 as a group and (iv) 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 (%)
ERBA Diagnostics Mannheim GmbH[2] Mallaustr 69-73 Mannheim, Germany 68219	20,034,713	72.5%
Transasia Bio-medicals Ltd.[2] Transasia House 8 Chandivali Studio Road Mumbai, India 400072	20,034,713	72.5%
Suresh Vazirani[2] Transasia House 8 Chandivali Studio Road Mumbai, India 400072	20,034,713	72.5%
Kishore "Kris" Dudani[2] Transasia House 8 Chandivali Studio Road Mumbai, India 400072	20,034,713	72.5%
Kevin D. Clark	218,699[3]	*
Charles R. Struby, Ph.D.[4]	0[5]	—
Arthur R. Levine	50,000[6]	*
Mark S. Deutsch[7]	128,000[8]	*
Steven E. Lufkin[9]	0[10]	—
Philippe Gadal, Pharm.D.	14,041[11]	*
John B. Harley, M.D., Ph.D.	165,000[12]	*
David M. Templeton	14,041[13]	*
All directors and executive officers as of March 25, 2011 as a group (7 persons)	20,903,128[14]	74.7%

* Represents beneficial ownership of less than 1%.

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

(2) Includes 20,026,313 shares of our common stock owned directly by ERBA and 8,400 shares of our common stock owned directly by Erba Lachema s.r.o. On September 2, 2010, ERBA, Transasia Bio-medicals Ltd., Erba Lachema s.r.o. and Messrs. Vazirani and Dudani filed a Schedule 13D as a "group," as such term is used in Section 13(d) of the Exchange Act. As set forth in the Schedule 13D, each of ERBA, Transasia and Messrs. Vazirani and Dudani may be deemed to have an aggregate beneficial ownership of 20,034,713, or 72.5%, of the issued and outstanding shares of our common stock; provided, however, that each of Messrs. Vazarani and Dudani disclaims such beneficial ownership except

to the extent of his pecuniary interest therein. Erba Lachema s.r.o. may only be deemed to be the beneficial owner of the 8,400 shares of our common stock that it owns directly.

(3) Includes options to purchase 100,000 shares of our common stock granted to Mr. Clark and 97,799 shares of our common stock owned by Mr. Clark through our 401(k) Plan.

(4) Effective September 3, 2010, Dr. Struby resigned as our Chief Executive Officer and President. However, Dr. Struby is included in this table because he is a Named Executive Officer.

(5) On December 20, 2010, we and Dr. Struby entered into a confidential general release of all claims, pursuant to which, among other things, Dr. Struby forfeited in its entirety the option to purchase 100,000 shares of our common stock which was previously granted to Dr. Struby. As a result, Dr. Struby no longer holds any options to purchase shares of our common stock.

(6) Includes options to purchase 50,000 shares of our common stock granted to Mr. Levine.

(7) Effective May 21, 2010, Mr. Deutsch resigned as our Chief Financial Officer. However, the shares of our common stock beneficially owned by Mr. Deutsch are included in this table because he is a Named Executive Officer.

(8) Includes options to purchase 110,000 shares of our common stock granted to Mr. Deutsch.

(9) Effective September 30, 2010, Mr. Lufkin resigned as our General Manager. However, Mr. Lufkin is included in this table because he is a Named Executive Officer.

(10) Includes options to purchase 14,041 shares of our common stock granted to Dr. Gadal.

(11) Includes options to purchase 165,000 shares of our common stock granted to Dr. Harley.

(12) Includes options to purchase 14,041 shares of our common stock granted to Mr. Templeton.

(13) Does not include the 128,000 shares of our common stock (including the options to purchase 110,000 shares of our common stock) beneficially owned by Mr. Deutsch because of his resignation as Chief Financial Officer, effective May 21, 2010.

Equity Compensation Plan Information

The following table sets forth information, as of December 31, 2010, 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	1,173,198	$2.09	3,427,990
Equity compensation plans not approved by stockholders	0	$ —	0
Total	1,173,198	$2.09	3,427,990

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

Controlling Stockholder

On September 1, 2010, ERBA purchased all of the approximately 72.4% of the outstanding shares of our common stock then owned by the Debregeas-Kennedy Group for an aggregate purchase price of approximately $15,000,000, or $0.75 per share. As a result of this share acquisition, ERBA now beneficially owns, directly or indirectly, approximately 72.5% of the outstanding shares of our common stock.

Certain Relationships and Related Transactions

We anticipate that, during the year ending December 31, 2011, we will sell test kits and instruments to, and may perform contract research and development services for, ERBA, Transasia Bio-Medicals Ltd., or

Transasia, the parent company of ERBA, and their affiliates. While we are not currently able to reasonably estimate the approximate aggregate dollar value associated with these sales and services, we believe that the aggregate dollar value associated with these sales and services could reasonably be expected to be in excess of $120,000.

Director Independence

Our Board of Directors has determined that three of its members—Philippe Gadal, Pharm.D., John B. Harley, M.D., Ph.D., and David M. Templeton—are "independent," as such term is defined in the applicable rules of the NYSE Amex 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, $5,000 per month from August 2009 to June 2010, and $2,000 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 2010, we accrued an aggregate payment of $10,000 to JK Autoimmunity under such license.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table sets forth the aggregate fees billed to us by PricewaterhouseCoopers LLP, or PwC, our principal accountant for the fiscal year ended December 31, 2009 and for the period from January 1, 2010 through June 11, 2010, and Grant Thornton LLP, which succeeded PwC as our principal accountant for the period from June 18, 2010 through December 31, 2010.

	For the years ended December 31,	
	2010	2009
Audit Fees	$217,400	$377,700
Audit-Related Fees	—	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	$217,400	$377,700

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:

Reports of Independent Registered Public Accounting Firms

Consolidated Balance Sheets as of December 31, 2010 and 2009

Consolidated Statements of Operations for the years ended December 31, 2010 and 2009

Consolidated Statements of Shareholders' Equity & Comprehensive Loss for the years ended December 31, 2010 and 2009

Consolidated Statements of Cash Flows for the years ended December 31, 2010 and 2009

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 Kevin Clark	Incorporated by reference to our Form 10-K filed on March 30, 2009.
10.4*	Amendment to Employment Agreement, dated as of August 31, 2010, by and between IVAX Diagnostics, Inc. and Kevin Clark	Incorporated by reference to our Form 10-Q filed on November 15, 2010.
10.5*	Second Amendment to Employment Agreement, dated as of September 3, 2010, by and between IVAX Diagnostics, Inc. and Kevin Clark	Incorporated by reference to our Form 10-Q filed on November 15, 2010.

Exhibit Number	Description	Method of Filing
10.6*	Employment Agreement, dated as of April 5, 2010, by and between IVAX Diagnostics, Inc. and Arthur Levine	Incorporated by reference to our Form 10-Q filed on August 16, 2010.
10.7*	Amendment to Employment Agreement, dated as of September 1, 2010, by and between IVAX Diagnostics, Inc. and Arthur Levine	Incorporated by reference to our Form 10-Q filed on November 15, 2010.
10.8*	Separation Agreement, dated as of May 3, 2010, by and between IVAX Diagnostics, Inc. and Mark Deutsch	Incorporated by reference to our Form 10-Q filed on May 14, 2010.
10.9*	Confidential General Release of All Claims, dated as of September 30, 2010, by and between IVAX Diagnostics, Inc. and Steve Lufkin	Incorporated by reference to our Form 10-Q filed on November 15, 2010.
10.10*	Confidential General Release of All Claims, dated as of December 20, 2010, by and between IVAX Diagnostics, Inc. and Charles Struby	Filed herewith.
10.11	1999 Performance Equity Plan	Incorporated by reference to our Form SB-2 filed on October 6, 1999.
10.12	1999 Stock Option Plan	Incorporated by reference to our Form 10-K filed on April 1, 2002.
10.13	2009 Equity Incentive Plan	Incorporated by reference to our Schedule 14A filed on May 8, 2009.
10.14	Form of Nonqualified Stock Option Agreement (Employee)	Incorporated by reference to our Form 8-K filed on June 16, 2009.
10.15	Form of Nonqualified Stock Option Agreement (Independent Director)	Filed herewith.
21.1	Subsidiaries of IVAX Diagnostics, Inc.	Filed herewith.
23.1	Consent of Independent Registered Public Accounting Firm — Grant Thornton LLP	Filed herewith.
23.2	Consent of Independent Registered Public Accounting Firm — PricewaterhouseCoopers LLP	Filed herewith.
31.1	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith.
31.2	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith.
32.1	Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	**
32.2	Certification of Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	**

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

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

SIGNATURES

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

IVAX DIAGNOSTICS, INC.

Dated: March 30, 2011

By: /s/ Kevin D. Clark
Kevin D. Clark,
Chief Executive Officer,
Chief Operating 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/Kevin D. Clark Kevin D. Clark	Chief Executive Officer, Chief Operating Officer and President (Principal Executive Officer)	March 30, 2011
/s/Arthur R. Levine Arthur R. Levine	Chief Financial Officer and Vice President-Finance (Principal Financial Officer) (Principal Accounting Officer)	March 30, 2011
/s/Suresh Vazirani Suresh Vazirani	Executive Chairman of the Board of Directors	March 30, 2011
/s/Kishore Dudani Kishore Dudani	Director	March 30, 2011
/s/Philippe Gadal, Pharm.D. Philippe Gadal, Pharm.D.	Director	March 30, 2011
/s/John B. Harley, M.D., Ph.D. John B. Harley, M.D., Ph.D.	Director	March 30, 2011
/s/David M. Templeton David M. Templeton	Director	March 30, 2011

We have made forward-looking statements in this annual report pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. 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: IVAX Diagnostics' ability to expand its businesses; IVAX Diagnostics' ability to increase stockholder value; IVAX Diagnostics' ability to generate positive cash flow or otherwise improve its 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 operations; the imposition on IVAX Diagnostics of positive and negative covenants under any financing arrangements, which could restrict various aspects of its business, operations and finances; the dilutive impact to existing IVAX Diagnostics stockholders of any issuance of equity securities, or securities convertible into shares of common stock; IVAX Diagnostics' ability to raise additional funds through issuing debt or equity securities or incurring indebtedness on acceptable terms or at all; IVAX Diagnostics' ability to successfully implement cost containment efforts and achieve a reduction in its costs; IVAX Diagnostics' ability to successfully implement initiatives to improve its manufacturing efficiencies and sales; economic, competitive, political, governmental and other factors affecting IVAX Diagnostics and its operations, markets and products; the success of IVAX Diagnostics' technological, strategic and business initiatives; the ability of the Mago® 4S to perform as expected; IVAX Diagnostics' ability to receive financial benefits or achieve improved operating results from and after the commercial release of the Mago® 4S; the ability of the Mago® 4S to be a factor in IVAX Diagnostics' growth; the ability of the Mago® 4S to expand the menu of test kits that IVAX Diagnostics offers; IVAX Diagnostics' ability to successfully market the Mago® 4S; IVAX Diagnostics' customers' integration of the Mago® 4S into their operations; IVAX Diagnostics' ability to achieve organic growth; IVAX Diagnostics' ability to identify or consummate acquisitions of businesses or products; IVAX Diagnostics' ability to integrate acquired businesses or products; IVAX Diagnostics' ability to achieve cost advantages from its own manufacture of instrument systems, reagents and test kits; IVAX Diagnostics' ability to grow beyond the autoimmune and infectious disease markets and to expand into additional diagnostic test sectors; IVAX Diagnostics' ability to consummate the investment contemplated by the stock purchase agreement on the contemplated terms, in the time frame anticipated, or at all; the net proceeds of the investment, whether or not the warrants are exercised, may not provide adequate cash resources to fund IVAX Diagnostics' operations or liquidity needs for the reasonably foreseeable future; IVAX Diagnostics' ability to achieve or sustain profitability from its operations or otherwise secure funds to provide the basis for its long-term liquidity; IVAX Diagnostics' use of the net proceeds from the investment, including, among other things, that IVAX Diagnostics has broad discretion in its use of the net proceeds from the investment, and that IVAX Diagnostics may not be successful in identifying or consummating acquisitions or other strategic opportunities and that any identified and consummated acquisition or other strategic opportunity may not result in the benefits anticipated or otherwise improve IVAX Diagnostics' financial condition, operating results or cash position; IVAX Diagnostics does not have the right to require ERBA Diagnostics Mannheim to exercise, or not exercise, the warrants contemplated by the investment, including, among other things, that the warrants may, or may not, be exercised in whole or in part, that ERBA Diagnostics Mannheim's decision whether or not exercise the warrants will be made by it based upon considerations it deems appropriate, such as, among other things, the future market price of IVAX Diagnostics' common stock, which is subject to volatility and a number of other factors beyond IVAX Diagnostics' control, and that ERBA Diagnostics Mannheim's interests in deciding whether or not to exercise the warrants may conflict with IVAX Diagnostics' interests; 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, 2010 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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