Erba® Diagnostics

2012 Annual Report

August 22, 2013

To Our Stockholders

2012 was a significant year for us. We changed our name from IVAX Diagnostics, Inc. to ERBA Diagnostics, Inc., to be consistent with the global network of ERBA companies. Another significant development was our acquisition of Drew Scientific, Inc. and JAS Diagnostics, Inc. We expect this acquisition to significantly increase our relevance to our customers, with the expanded product offerings in the areas of Chemistry, Hematology and Diabetes testing globally.

We can best describe 2012 as the beginning of our transformation – the year in which we initiated several new efforts to strengthen our future performance. As we move forward in our transformational journey, we have three key areas of focus:

1. Revenue growth through planned expansion of product range and market reach;
2. Consolidate manufacturing and marketing operations to drive operational efficiency; and
3. Integrate and optimize financial systems across all companies.

Revenue Growth:

As mentioned above, our acquisition of Drew Scientific and JAS Diagnostics has expanded our product portfolio, giving us the opportunity to serve a much larger market and more customers than our original product portfolio. While we intend to continue to leverage our existing customer base in the United States and expand our offering to them, we believe that the product portfolio of Drew Scientific and JAS Diagnostics positions us to expand our market segments within the United States and opens up a significant space for us in the emerging markets across all our offerings. The field of diabetes is of particular focus, as the incidence of diabetes is expected to increase at a substantial rate over the next 15 years and is expected to affect 550 million people by 2030 (an increase from the 336 million people currently affected), as reported by the International Federation of Diabetes. This increase is predominantly expected to occur in Asia, Africa and South America due to changing lifestyles where over 60% of the people have not yet been diagnosed. With our strong presence in these markets through the global network of ERBA companies, we expect our Diabetes, Hematology and Chemistry range of products will generate an increased revenue stream in the future.

In the next few months, we plan to launch following two new exciting products for global markets:

i) Hb-Vario, a new, advanced technology analyser for Diabetes and Hemoglobin variants; and

ii) LISA XL, a new Immunoassay analyser.

With an aim to expand our marketing efforts in Latin and South America, we have recently opened a new office in Mexico City for marketing offices and training center. We are in the process of registering several products with the applicable regulatory bodies in Mexico and other countries.

Manufacturing Consolidation:

I am pleased to inform you that we have started the process of consolidating manufacturing and administrative operations at our recently expanded 45,000 sq. ft. facility at Miami Lakes, Florida, and that our first initiative to consolidate the operations of the Drew Scientific facility located in the United Kingdom has been completed. We expect to complete the consolidation of the operations of the Drew Scientific facility in Dallas, Texas, by the end of the year. I am confident that our efforts to consolidate our manufacturing operations will provide us with the opportunity to achieve significant operational efficiency and to improve our competitiveness in the global marketplace.

Integrate and Optimize Financial Systems:

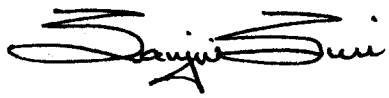
We have started the process of integrating our financial systems to one ERP platform and expect to complete it by the end of the year. We believe that the platform integration will optimize all of our processes from sales and distribution management, supply chain, manufacturing and financial reporting, drive efficiencies across all functions and improve our service to our customers and stakeholders.

We are currently in compliance with all FDA requirements for policies, procedures, processes, documentation, manufacturing, quality control, and supporting systems. Additionally, we have started a program to continuously review all our policies, procedures and processes in an effort to improve efficiency on an ongoing basis. We believe that this program will provide us with additional capacity to enable growth and expand our business.

Looking forward, we believe that 2013 will be a year of consolidation and growth for us, as we continue to work through the integration of our five separate subsidiaries across all functions in an effort to drive growth and efficiency. During January 2013, we reorganized our operations along functional lines in an effort to break down silos related to the conduct of our business through our five separate subsidiaries. We believe that this reorganization will better position us to meet the goals we have set for 2013 and beyond. In addition, in October 2012, we appointed Mohan Gopalkrishnan as Vice President – Operations. With a lifelong career in the health care industry, we expect that Mohan's experience will strengthen our management team and improve efficiencies to help our company reach its full potential. We plan to further strengthen our management team with experienced professionals in all key functions and build a strong team that is performance driven.

We believe that our financial condition continues to be healthy. The health care industry is one of the few growth industries today. Our goal is to be a recognized presence in the health care industry, while continuing to provide an important service to mankind – proper disease diagnosis. We believe the future for ERBA Diagnostics remains an exciting one, and we look forward to sharing our progress with you along the journey.

Respectfully yours,



Sanjiv Suri,
Interim Chief Executive Officer

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

FORM 10-K

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

**For the fiscal year ended
December 31, 2012**

Commission File Number 1-14798

ERBA 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.)

14100 NW 57th Court, Miami Lakes, Florida 33014
(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 MKT**
(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, 2012, was approximately $4,920,954 computed by reference to the price at which the common equity was last sold on the NYSE MKT on such date.

As of June 7, 2013, there were 43,658,221 shares of common stock outstanding.

Documents Incorporated by Reference:

None.

ERBA Diagnostics, Inc.

Annual Report on Form 10-K
for the year ended December 31, 2012

TABLE OF CONTENTS

[This page intentionally left blank.]

PART I

ITEM 1. BUSINESS

General. We are the parent corporation of the following five subsidiaries:

- Delta Biologicals, S.r.l.;
- Diamedix Corporation;
- Drew Scientific, Inc.;
- ImmunoVision, Inc.; and
- JAS Diagnostics, 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, infectious diseases, clinical chemistry, hematology and diabetes testing. These tests, which are designed to aid in the identification of the causes of illness and disease, assist physicians in selecting appropriate patient treatment. Our tests are based on a wide variety of technologies including Enzyme Linked ImmunoSorbent Assay, or ELISA, technology, clinical chemistry, hematology and cell separation, as well as HPLC separations, all of which are clinical testing methodologies used worldwide. Autoimmune and infectious disease 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, later in 2011, we began to market the instrument in the United States. We also develop, manufacture and market raw materials, such as antigens used in the production of diagnostic kits.

Our management reviews financial information, allocates resources and manages the business as two segments defined by geographic region. One segment — the domestic region — contains our subsidiaries located in the United States and corporate operations. Our other segment — the European 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, acquired in 1991, was established in 1980. From its facility located in Pomezia, Italy, it manufactures scientific and laboratory instruments, including its proprietary Mago® 4, Mago® 4S and Mago® Plus systems, which include hardware, reagents and software. 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® 4S, Mago® Plus and Aptus® systems, in association with over 250 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, 2012, approximately 42.8% of Delta's revenue generated from customers in Italy was revenue from government owned hospitals and the remaining 57.2% 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 Corporation 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 approximately 100 assays that the United States Food and Drug Administration, or FDA, has cleared. Our autoimmune product line consists of approximately 50 ELISA test kits and approximately 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 Corporation acquired ImmunoVision in 1995. ImmunoVision is located in Springdale, Arkansas.

Drew Scientific was established in 1980. As described in further detail below, we acquired Drew Scientific on October 3, 2012. Drew Scientific is a diagnostics company specializing in the design, manufacture and distribution of instruments for blood cell counting and blood analysis. Drew Scientific is focused on providing instrumentation and consumables for the physician office and veterinary office laboratories. Drew Scientific also supplies the reagent and other consumable materials needed to operate the instruments. Drew Scientific sells diabetic testing products including the DS5 instrument, dispenser and associated reagent kit, which measure long-term glucose control in diabetic patients (Hb1Ac). The DS5 instrumentation system, with its small size and ease of use, is sold principally into main laboratory, clinic or satellite laboratory settings. The DS5 instrument and associated reagent kit provides for the in vitro measurement of certain genetic diseases of the blood. In the United States, this instrument is available for research only. Additionally, Drew Scientific offers a broad array of equipment for use in the field of human and veterinary hematology. Drew Scientific's Excell product lines are for use in the field of human hematology, and its Hemavet product line is for use in the veterinary field. Drew Scientific has facilities located in Waterbury, Connecticut, and Dallas, Texas.

JAS Diagnostics was established in 2000. As described in further detail below, we acquired JAS Diagnostics on October 3, 2012. JAS Diagnostics specializes in the manufacture of a broad range of liquid stable, diagnostics chemistry reagents used for in vitro diagnostics testing. Many of these reagents are single vial stable, which we believe offer ease of use, increased speed of results and extended on-board stability. JAS Diagnostics' reagents are sold through distributors and directly to end users customers — physician, reference, hospital and veterinary diagnostic testing laboratories. JAS Diagnostics has many general chemistry reagents that can be used on numerous open system chemistry instrument analyzers. JAS Diagnostics is located in Miami Lakes, Florida.

Acquisition. On October 3, 2012, we acquired all of the issued and outstanding shares of capital stock of Drew Scientific from a subsidiary of Escalon Medical Corp. ("Escalon"). The acquired businesses had been commonly known as the Escalon Clinical Diagnostics Business, which consisted of Drew Scientific (located in Waterbury, Connecticut, and Dallas, Texas), and its wholly-owned subsidiaries JAS Diagnostics, Inc. (located in Miami Lakes, Florida), and Drew Scientific Limited Co. (at the time located in Barrow-in-Furness, United Kingdom).

Name Change. As approved by our stockholders at the Annual Meeting of Stockholders held on June 15, 2012, and as previously approved by our Board of Directors, our company's name was changed from "IVAX Diagnostics, Inc." to "ERBA Diagnostics, Inc."

Merger. On November 21, 2000, IVAX Corporation and the pre-merger IVAX Diagnostics, Inc., which then was a wholly-owned subsidiary of IVAX Corporation and which was incorporated in 1996 by IVAX Corporation 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 then issued and outstanding shares of our common stock became owned by IVAX Corporation 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 Corporation, 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 Corporation to be merged into a wholly-owned subsidiary of Teva. On January 26, 2006, the merger was consummated and IVAX Corporation became a wholly-owned subsidiary of Teva. As a result of the merger, Teva, indirectly through its wholly-owned IVAX Corporation subsidiary, owned approximately 72.3% of the then 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 then outstanding shares of our common stock then owned by Teva, indirectly through its wholly-owned IVAX Corporation subsidiary. 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 Mannheim, 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 then 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, the consummation of the various transactions contemplated by the investment made by ERBA Mannheim pursuant to that certain Stock Purchase Agreement, as further described below, including ERBA Mannheim's purchase from us, and our issuance to ERBA Mannheim, of an aggregate of 15,333,334 shares of our common stock, and ERBA Mannheim's exercise, in part, of the Warrant, as further described below, for 600,000 shares of our common stock, ERBA Mannheim now beneficially owns, directly or indirectly, approximately 82.4% 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.

Our historical focus was specifically centered on the immunoassay segment of the in vitro diagnostics market. 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. Further, our focused effort remains on the market for autoimmune and infectious disease immunoassay products. However, now with the acquisition of Drew Scientific's and JAS Diagnostics' well known brands of "DREW" and "JAS," respectively, analyzers and reagents for testing of HbA1c, hematology and clinical chemistry tests, we have significantly expanded our market. Drew Scientific has been in the business of diabetes management and hematology since 1980.

This acquisition marks our entry into the important and strategic segment of diabetes management, which has so far been dominated by four companies. It is estimated that diabetes affects close to 250 million people worldwide. In North America, nearly 23 million people are currently affected. In the BRIC countries, the numbers are even larger, with 12 million in Brazil, 12.6 million in Russia, 61 million in India and 90 million in China. The World Health Organization has estimated that the worldwide prevalence of diabetes is approximately 7% of the worldwide population.

Drew Scientific sells its chromatography based HbA1c analyzers along with hematology and clinical chemistry solutions in 82 countries worldwide. Drew Scientific holds FDA clearance for its HbA1c, hematology and clinical chemistry products and solutions and further has regulatory clearances in approximately 72 countries.

We see the opportunity of entering the critical and rapidly growing segment of diabetes management. ERBA Mannheim and its affiliates enjoy leadership positions in high burden countries such as India and have substantial marketing and distribution infrastructure in North America, Europe, Asia, Africa and Latin America, which we intend to leverage. Drew Scientific also provides instrumentation and consumables for the physician office labs, small hospital labs and veterinary research laboratories in the diagnostics segment of clinical chemistry and hematology. Included in this market is JAS Diagnostics' broad range of liquid stable, clinical chemistry and hematology reagents for human and veterinary application.

JAS Diagnostics' reagents are sold through distributors and directly to our end-user customers' (physician, reference, hospital and veterinary) diagnostic testing laboratories. JAS Diagnostics sells "JAS" labeled finished product reagent kits, along with private label reagents and various forms of bulk/subassembly reagents to other manufacturers for sale under their labels.

JAS Diagnostics' many general chemistry reagents can be used on most open system chemistry instrument analyzers, through our specific instrument applications. Additionally, JAS Diagnostics' reagents are marketed for use as instrument specific reagent lines, such as in instrument reagent containers and bar coded for use on the Olympus 400 and 600 series, Mindray BS-200, Alfa Wassermann ACE/ALERA chemistry analyzers, among others.

Research and Development. We devote substantial resources for research and development. We incurred $1.1 million in 2012 and $1.5 million in 2011 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 their respective regulatory approval. We are continuing our research and development in 2013, both for making improvements to the Mago® 4 and Mago® 4S as well as planning for the next-generation instrument. In the fourth quarter of 2011, a subsidiary of the Company entered into a contract research and development agreement with ERBA Mannheim for a total of Euro 754,700, pursuant to which ERBA Mannheim has agreed to pay the subsidiary a total amount of Euro 133,000, equivalent to approximately $186,000, during the fourth quarter of 2011 and an additional Euro 621,700 (equivalent to approximately $799,000) during 2012 for the results of certain research and development. 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 primarily 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. In 2011, we began to distribute our products in the United States through certain independent distributors. 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 a small number of 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.

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, Bio-Rad Laboratories, DiaSorin, INOVA, Alere, Meridian Bioscience and The Binding Site.

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 June 7, 2013, we had 99 full time employees, of whom 7 were managerial, 56 were technical and manufacturing, 11 were administrative and 25 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. Until 2010, the Mago® Plus instrument had 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 be our primary platforms for marketing our ELISA kits. The acquisition of Drew Scientific brought along 18 patents all surrounding the instrumentation and reagents for the DS360, Ds5, 2280 and the Hemavet for the diabetes and hematology markets.

On June 15, 2012, we entered into a use of name license agreement with ERBA Mannheim granting a royalty-free, non-exclusive license to use the name "ERBA" for an annual fee of one dollar. The license agreement will be terminated upon the earlier of (a) the transfer by ERBA Mannheim to us of all of ERBA Mannheim's rights, title and interest in and to the use of the name and any stylized logos or marks associated with the name (the date that such transfer becomes effective, the "Transfer Date") and (b) such time, if any, as ERBA Mannheim no longer owns, directly or indirectly, shares of our common stock representing more than 50% of the issued and outstanding shares of such stock (the "Share Threshold Date"). Furthermore, ERBA Mannheim may terminate the license agreement at any time after June 15, 2013 and prior to the earlier of the Transfer Date and the Share Threshold Date: (a) upon providing us 180 days prior written notice of its intent to terminate and the date upon which the license agreement shall terminate; or (b) upon providing us 30 days prior written notice of any breach of the license agreement by us, which breach remains uncured at the end of such 30 day period. The termination of this license by ERBA Mannheim 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.erbadiagnostics.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.

We may not have adequate cash resources to fund our operations or liquidity needs for the reasonably foreseeable future.

On April 8, 2011 we entered into, and on June 30, 2011 we consummated the initial transactions under, a stock purchase agreement with ERBA Mannheim, pursuant to which we agreed to sell and issue to ERBA Mannheim an aggregate of 20,000,000 shares of our common stock for an aggregate purchase price of $15,000,000, or $0.75 per share, and warrants to purchase an additional 20,000,000 shares of our common stock with a five-year term and an exercise price per share equal to $0.75. The warrants are exercisable only to the extent that shares of our common stock have been purchased under the stock purchase agreement. The stock purchase agreement was amended on December 29, 2011 and on October 3, 2012. For purposes of this Annual Report on Form 10-K, references to the stock purchase agreement shall mean the stock purchase agreement as so amended.

Through December 31, 2012, under the stock purchase agreement, we have issued and sold to ERBA Mannheim a total of 15,333,334 shares of our common stock for aggregate gross proceeds of $11,500,000. As of December 31, 2012, under the stock purchase agreement, we remained obligated to issue and sell, and ERBA Mannheim remained obligated to purchase, another 4,666,666 shares of our common stock for an aggregate purchase price of $3,500,000, on the date that is 60 days after the date on which a majority of the independent directors on our board of directors determines by vote or written consent that such issuance, sale and purchase shall occur and causes notice thereof to be delivered to ERBA Mannheim.

Through December 31, 2012, under the stock purchase agreement, ERBA Mannheim has exercised warrants by paying to us an aggregate exercise price of $450,000 and, in connection therewith, we issued to ERBA Mannheim 600,000 shares of our common stock. As of December 31, 2012, under the stock purchase agreement, warrants to purchase a total of 19,400,000 shares of our common stock remained unexercised, and warrants were exercisable for 14,733,334 shares of our common stock.

The net proceeds of the investment contemplated by the stock purchase agreement may not provide adequate cash resources to fund our operations or liquidity needs for the reasonably foreseeable future.

On March 1, 2013, we entered into a loan agreement with Citibank, N.A., which provides for a secured, revolving credit facility of up to $2,000,000. The line of credit may not provide adequate cash resources to fund our operations or liquidity needs for the reasonably foreseeable future.

In addition to the sources of equity and debt financing described above, we have implemented strategies to reduce our expenses and in an effort to improve our cash flows.

We cannot guarantee that we can generate net income, increase revenues, continue to reduce expenses, improve our cash flow or otherwise improve our liquidity, whether from existing operations, strategic initiatives or existing or possible future sources of liquidity, including, without limitation, from the line of credit or the investment contemplated by the stock purchase agreement, issuing debt or equity securities, incurring indebtedness or curtailing or reducing our operations, and, if we cannot do so, then we may not be able to survive and any investment in our company may be lost.

The remaining transactions contemplated by the investment under the stock purchase agreement may not be consummated on the contemplated terms, in the time frame anticipated, or at all.

The remaining transactions contemplated by the investment under the stock purchase agreement may not be consummated on the contemplated terms, in the time frame anticipated, or at all. While the decision to initiate the consummation of the issuance and sale of the remaining shares of our common stock pursuant to the stock purchase agreement is at the discretion of a majority of the independent directors on our board of directors, ERBA Mannheim, while obligated under the stock purchase agreement to do so, will make its own decision

whether, or not, to consummate the purchase of the remaining shares of our common stock pursuant to the stock purchase agreement. Additionally, the decision to exercise the warrants will be made by ERBA Mannheim based upon considerations it deems appropriate, which may include, among other things, the future market price of our common stock, which is subject to volatility and a number of other factors, many of which are beyond our control. Further, when making any such decision to purchase the remaining shares of our common stock or to exercise the warrants, ERBA Mannheim's interests may conflict with our interests. Further, the warrants may not be exercised, in whole or in part. If any of the foregoing factors was to occur, then we may not have adequate cash resources to fund our operations or liquidity needs for the reasonably foreseeable future.

Our October 2012 acquisition of businesses commonly known as Drew Scientific and JAS Diagnostics represents our largest acquisition, has not yet been integrated into our operations and may expose us to risks relating to evaluations of our internal controls.

In October 2012, we completed the acquisition from Escalon Medical Corporation of the businesses commonly known as Drew Scientific and JAS Diagnostics, our largest and most significant acquisition to date. Our future success is dependent, in part, upon our ability to effectively integrate these acquired businesses into our operations. In our efforts to integrate these acquired businesses into our operations, we may experience difficulties with customers, personnel, systems integration or otherwise. We cannot provide any assurance that these acquired businesses will be successfully integrated into our operations, enhance our competitive position or business prospects or that the anticipated benefits will be realized. Our efforts to integrate these acquired businesses may expose risks relating to the acquired businesses' internal controls, as these acquired businesses are decentralized with locations in Connecticut, Florida, Texas and previously the United Kingdom. As permitted by the applicable rules and regulations of the Securities and Exchange Commission, our management's evaluation of and conclusion on the effectiveness of our internal control over financial reporting as of December 31, 2012 did not include the internal control over financial reporting of the businesses commonly known as Drew Scientific and JAS Diagnostics. However, as of December 31, 2013, we will be required to do so. We may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting.

Acquisitions, such as our October 2012 acquisition of the businesses commonly known as Drew Scientific and JAS Diagnostics, and our efforts to integrate these acquired businesses may disrupt our business operations, distract our management and may not proceed as planned.

Acquisitions, such as our October 2012 acquisition from Escalon Medical Corporation of the businesses commonly known as Drew Scientific and JAS Diagnostics, and our efforts to integrate these acquired businesses may use significant resources, result in disruptions to our business operations, result in distractions of our management and not proceed as planned and could expose us to unforeseen liabilities. Acquisitions, such as our October 2012 acquisition from Escalon Medical Corporation of the businesses commonly known as Drew Scientific and JAS Diagnostics, and our efforts to integrate these acquired businesses involve a number of special problems and risks, including, but not limited to:

- difficulty integrating acquired technologies, products, services, operations, customers and personnel with the existing businesses;
- diversion of management's attention in connection with integrating the acquired businesses;
- strain on managerial and operational resources as management tries to oversee larger operations;
- difficulty implementing and maintaining effective internal control over financial reporting at the acquired businesses, particularly in light of the decentralized locations in Connecticut, Florida, Texas and previously the United Kingdom; and
- exposure to unforeseen liabilities of the acquired businesses.

As a result of these or other problems and risks, businesses we acquire, such as our October 2012 acquisition from Escalon Medical Corporation of the businesses commonly known as Drew Scientific and JAS Diagnostics, may not produce the revenues, earnings, cash flows or business synergies that we anticipated, and the products, services or technologies of the acquired businesses may not perform as we

expected. As a result, we may incur higher costs and realize lower revenues and earnings than we had anticipated. We may not be able to successfully address these problems, integrate the acquired businesses or generate sufficient revenue to offset the associated costs or other negative effects on our business.

Our growth through acquisitions has placed, and is expected to place, significant demands on us.

We have grown our business, including through acquisitions. Businesses that grow rapidly often have difficulty managing their growth. Our growth has placed and is expected to continue to place significant demands on our management, on our accounting, financial, information and other systems and on our business. We need to continue recruiting and employing experienced executives and key employees capable of providing the necessary support. In addition, we will need to continue to improve our financial, accounting, information and other systems in order to effectively manage our growth. We cannot assure that our management will be able to manage our growth effectively or successfully, or that our financial, accounting, information or other systems will be able to successfully accommodate our external and internal growth. Our failure to meet these challenges could materially impair our business.

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, 2012, we recorded net revenues of $19.3 million and net loss of $1.6 million. For the year ended December 31, 2011, we recorded net revenues of $16.8 million and net loss of $3.3 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 2011 and 2010, we enacted various measures to reduce expenses in order to improve future cash flow. As a result, our operating results improved in 2012 from the operating results achieved during 2011. During 2011, we also entered into the stock purchase agreement with ERBA Mannheim. On March 1, 2013, we also entered into the line of credit with Citibank, N.A. 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, including, without limitation, from the line of credit and the investment contemplated by the stock purchase agreement. 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, including, without limitation, from the line of credit or the investment contemplated by the stock purchase agreement, 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.

If we are not able to remediate the material weakness relating to our internal controls over financial reporting, then the timing and accuracy of our financial reporting could be adversely affected and current and potential stockholders could lose confidence in our financial reporting, which would harm our business and the price of our common stock.

As described in Item 9A, *Controls and Procedures*, included in this Annual Report on Form 10-K, we disclosed a material weakness in our internal control over financial reporting related to inadequate staffing of our financial accounting office. As a result of our inadequate staffing of our financial accounting office, among other things, at times we have been unable to provide timely account reconciliations. Our remediation efforts to address this material weakness are ongoing and include, among other things, hiring additional qualified personnel and evaluating or undertaking certain improvements to our systems and processes which, if successful, we believe will be sufficient to provide us with the ability to remediate or cure such material weakness in the future.

While remediating this material weakness is a very high priority for our management and the audit committee of our board of directors, we cannot assure you that we will not encounter further instances of breakdowns in

our internal control over financial reporting. Public disclosure of this material weakness or a failure to promptly complete our remediation effort could cause our common stock price to fall. Additionally, our inability to maintain the operating effectiveness of the financial accounting office could result in material misstatements to our financial statements or other disclosures, which could have an adverse effect on our business, financial condition or results of operations.

If we fail to timely cure our non-compliance with the continued listing standards of the NYSE MKT or, whether or not timely cured, if we fall below the continued listing standards of the NYSE MKT again, our common stock could be delisted from the NYSE MKT.

On April 17, 2013, we received a letter from the NYSE MKT, or the Exchange, stating that the Exchange determined that we were not in compliance with Sections 134 and 1101 of the Exchange's Company Guide due to our failure to timely file our Annual Report on Form 10-K for the year ended December 31, 2012 with the Securities and Exchange Commission. The letter also stated that our failure to timely file our Annual Report on Form 10-K for the year ended December 31, 2012 was a material violation of our listing agreement with the Exchange and, therefore, pursuant to Section 1003(d) of the Company Guide, the Exchange was authorized to suspend and, unless prompt corrective action was taken, remove our securities from the Exchange. We were afforded the opportunity to submit a plan of compliance to the Exchange and, on April 29, 2013, we presented our plan of compliance to the Exchange. On May 10, 2013, the Exchange notified us that it accepted our plan of compliance and granted us an extension until July 16, 2013, or the Plan Period, to regain compliance with the continued listing standards of the Company Guide. We will be subject to periodic review by the Exchange during the Plan Period. Failure to make progress consistent with the plan of compliance or to regain compliance with the continued listing standards of the Company Guide by the end of the Plan Period could result in our common stock being delisted from the Exchange. We are working diligently to regain compliance with the Company Guide by July 16, 2013.

On May 17, 2013, we received a letter from the Exchange, stating that the Exchange determined that we were not in compliance with Sections 134 and 1101 of the Company Guide due to our failure to timely file our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013 with the Securities and Exchange Commission. The letter also stated that our failure to timely file our Quarterly Report on Form 10-Q for the quarter ended March 31, 2013 was a material violation of our listing agreement with the Exchange and, therefore, pursuant to Section 1003(d) of the Company Guide, the Exchange was authorized to suspend and, unless prompt corrective action was taken, remove our securities from the Exchange. We were afforded the opportunity to submit a plan of compliance to the Exchange and, on May 31, 2013, we presented our plan of compliance to the Exchange. We expect the Exchange will soon notify us about our plan of compliance. Failure to make progress consistent with the plan of compliance or to regain compliance with the continued listing standards of the Company Guide by August 15, 2013 could result in our common stock being delisted from the Exchange. We are working diligently to regain compliance with the Company Guide by August 15, 2013.

Pursuant to Section 1009(h) of the Company Guide, if we, within twelve (12) months of the end of the Plan Period (including any early termination of the Plan Period under the procedures set forth in Section 1009(g) of the Company Guide), are again determined to be below continued listing standards, then the Exchange staff will examine the relationship between the two incidents of falling below continued listing standards and re-evaluate our method of recovery from the first incident. In such an instance, the Exchange will then take appropriate action, which, depending upon the circumstances, may include truncating the procedures set forth in Section 1009 of the Company Guide or immediately initiating proceedings to delist our common stock from the NYSE MKT.

Concerns regarding the Italian government fiscal and debt crises could have a material adverse effect on our operating results.

A substantial portion of our accounts receivable are concentrated in Italy and may be affected by the recent fiscal and debt crises facing the Italian government. As of December 31, 2012 and December 31, 2011, $4.4 million and $4.2 million, respectively, of our total net accounts receivable were due from customers of our Italian subsidiary, the majority of which are located in Italy. Of our total net accounts receivable, 27% at December 31, 2012 and 36% at December 31, 2011 were due from hospitals and laboratories controlled by

the Italian government. We maintain 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 our periodic credit evaluations of our customers' financial condition.

Recently, the Italian government has been experiencing severe fiscal and debt crises and a recession, including its increasingly uncertain ability to service its sovereign debt obligations, caused in part by the declining global markets and economic conditions. Accordingly, we are subject to certain economic, business and, in particular, credit risk if our customers located in Italy which are hospitals or laboratories controlled by the Italian government do not pay amounts owed to us, extend payment cycles even further or ask us to accept a lower payment amount than is owed to us. Our current allowances for doubtful accounts may not be adequate and we may be required to make additional allowances, which would adversely affect, and could materially adversely affect, our operating results in the period in which the determination or allowance is or was made. Any of these factors could materially and adversely affect our business, prospects, operating results, financial condition and cash flows in the near term.

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.

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, 2012 and 2011, our accounts receivable were $7.2 million and $6.7 million, respectively, and our allowance for doubtful accounts was $0.8 million and $0.7 million, respectively. 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.

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® 4 and 4S instruments 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 upgraded versions 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 began to market in the United States in 2011. We received clearance in the first quarter of 2011 from the FDA on the 510(k) premarket submission that we filed for the Mago® 4S. 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 sales of existing products or development of new products.

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 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. During October 2011, we obtained "CE Marking" for a number of hepatitis kits that we intend to manufacture and market beginning in 2013. However, there remains a risk that we will not be able to manufacture and market these products successfully or within the anticipated timeframe. 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. At December 31, 2012, we had approximately $0.3 million of intangible assets relating to the hepatitis technology product license. Although we obtained "CE Marking" during October 2011 for a number of hepatitis kits that we intend to manufacture and market, the delays in obtaining "CE Marking", 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 beginning in 2013, 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.

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

We have sought to differentiate ourselves from our competitors through our proprietary instrument systems. While some of our competitors offer proprietary instruments, other competitors use third parties to manufacture these instruments for them. We manufacture our Mago® 4 and Mago® 4S instruments at Delta, our wholly-owned subsidiary in Italy. Additionally, our wholly-owned subsidiary located in Springdale, Arkansas, ImmunoVision, produces certain autoimmune reagents and our wholly-owned subsidiary located in Miami, Florida, 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 2012, we incurred approximately $1.1 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 in the United States, 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® 4 and Mago® 4S 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, 2011 and December 31, 2012, we had approximately $0.3 million of intangible assets. During the year ended December 31, 2012, the balance of 100,000 Euro (equivalent to approximately $132,000) was offset against the accounts receivable owed to us from the Italian diagnostics company. While we obtained "CE Marking" during October 2011 for a number of hepatitis kits and we believe that we will be able to bring these hepatitis test kits to market in 2013, 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 2012 or 2011. However, a continued decline in our market capitalization or sales by ImmunoVision 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 have made and are expected to continue 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.

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, 2012 and 2011, Delta represented 26% and 31%, 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, 2012 and 2011, 26% and 31%, 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 indebtedness may impact our financial condition and results of operations and the terms of our indebtedness may limit our activities.

As of December 31, 2012, we had approximately $823,000 of indebtedness outstanding under the previously existing line of credit pursuant to the loan agreement into which Diamedix has entered with City National Bank of Florida. On March 1, 2013, we closed down the previously existing line of credit and we entered into a new loan agreement with Citibank, N.A., which provides for a secured, revolving credit facility of up to $2,000,000. Subject to applicable restrictions in the loan agreement, we may incur indebtedness in the future. Our level of indebtedness will have several important effects on our future operations, including, without limitation, that we may be required to use a portion of our cash flow from operations for the payment of principal and interest due on our outstanding indebtedness, that our outstanding indebtedness and leverage will increase the impact of negative changes in general economic and industry conditions, as well as competitive pressures, and that our ability to obtain additional financing for working capital, capital expenditures or general corporate purposes may be impacted.

Our indebtedness outstanding under the line of credit bears interest at a floating rate tied to LIBOR. Accordingly, if interest rates increase, whether generally or as the result of our lender's requirement, then the amount of the interest payments on our floating rate indebtedness will also increase. General economic conditions, industry cycles and financial, business and other factors affecting our operations, many of which are beyond our control, may affect our future performance. As a result, these and other factors may affect our ability to make principal and interest payments on our indebtedness.

Amounts outstanding under the new line of credit with Citibank, N.A. are collateralized by all of our assets and all of the assets of our wholly-owned subsidiaries located in the United States — Diamedix, ImmunoVision and Drew Scientific. In addition, each of Diamedix, ImmunoVision and Drew Scientific has guaranteed the repayment of amounts outstanding under the new line of credit. Further, Transasia, our indirect parent company, has also guaranteed the repayment of amounts outstanding under the new line of credit.

The loan agreement, pursuant to which the new line of credit with Citibank, N.A. has been made available to us, contains certain positive and negative restrictive covenants which will affect, and in certain respects will limit or prohibit, our ability to, among other things, create or permit any liens on our assets, engage in business activities substantially different than those in which we are currently engaged, enter into certain transactions in which we are not the surviving entity, transfer or sell our assets other than in the ordinary course of business, enter into certain obligations as surety or guarantor, or permit a change of control. In addition, the new loan agreement requires us to maintain an enumerated level of a capital base and to maintain an enumerated leverage ratio.

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 Mannheim may be deemed to control our company.

ERBA Mannheim beneficially owns, directly or indirectly, approximately 82.4% of the issued and outstanding shares of our common stock. Further, assuming the full consummation of the investment under the stock purchase agreement, as amended, including the full exercise of the warrant, ERBA Mannheim would currently beneficially own, directly or indirectly, approximately 88.7% 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 Mannheim, 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 Mannheim, currently serves as executive Chairman of our board of directors, and Sanjiv Suri, the President International Business of ERBA Mannheim, and Kishore "Kris" Dudani, the Marketing and Business Development Representative — South, Central and Latin America of ERBA Mannheim, currently serve as members of our board of directors. Transasia Bio-Medicals Ltd. is the parent company of ERBA Mannheim.

At our 2011 annual meeting of stockholders, the requisite super-majority of our minority stockholders approved a proposal pursuant to which "business combinations" with ERBA Mannheim and its affiliates and associates have been approved under Section 203 of the Delaware General Corporation Law.

At our 2011 annual meeting of stockholders, the requisite super-majority of our minority stockholders approved a proposal pursuant to which "business combinations" with ERBA Mannheim and its affiliates and associates have been approved under Section 203 of the Delaware General Corporation Law. As a result of such approval, there is not a time limit for any "business combinations" with ERBA Mannheim and its affiliates and associates or a maximum number, or dollar value, of shares of our common stock, warrants and other convertible securities, debentures and any other securities that could be sold to ERBA Mannheim and its affiliates and associates, and such approval included, among other transactions and opportunities, short-form mergers under Section 253 of the Delaware General Corporation Law. However, such stockholder approval did not eliminate the need for approval by our board of directors of financing transactions or other strategic opportunities between us and ERBA Mannheim and its affiliates and associates. Accordingly, any financing transaction or other strategic opportunity with ERBA Mannheim and its affiliates and associates would require the approval of the majority of the non-interested members of our board of directors, who, consistent with their fiduciary duties as members of the board of directors, would evaluate all transactions with ERBA Mannheim and its affiliates and associates to ensure that such transactions are on market terms and in the best interests of us and all of our stockholders. In addition, such stockholder approval constitutes approval of any applicable transaction or opportunity solely for purposes of Section 203 of the Delaware General Corporation Law. Accordingly, notwithstanding such stockholder approval, any transaction or opportunity which we may explore in the future with ERBA Mannheim or its affiliates or associates that requires stockholder approval under any other law, rule or regulation would continue to be subject to stockholder approval, which approval may be obtained by means of a vote of our stockholders at an annual or special meeting of stockholders or, if permitted and deemed advisable by our board of directors, by written consent of holders of shares representing at least the minimum number of votes which would be required for the transaction or opportunity to be approved if it was considered and voted upon at any such meeting.

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

As approved by our stockholders at our 2012 annual meeting of stockholders held in June 2012, and as previously approved by our board of directors, we changed the name of our company from "IVAX Diagnostics, Inc." to "ERBA Diagnostics, Inc." In connection with our name change, on June 15,

2012, we entered into a use of name license agreement with ERBA Mannheim granting us a royalty-free, non-exclusive license to use the name "ERBA" for an annual fee of one dollar. The license agreement will be terminated upon the earlier of the transfer by ERBA Mannheim to us of all of ERBA Mannheim's rights, title and interest in and to the use of the name and any stylized logos or marks associated with the name, or otherwise known as the transfer date, and such time, if any, as ERBA Mannheim no longer owns, directly or indirectly, shares of our common stock representing more than 50% of the issued and outstanding shares of our common stock, or otherwise known as the share threshold date. Furthermore, ERBA Mannheim may terminate the license agreement at any time after June 15, 2013 and prior to the earlier of the transfer date and the share threshold date, upon providing us with 180 days prior written notice of its intent to terminate and the date upon which the license agreement shall terminate or upon providing us with 30 days prior written notice of any breach of the license agreement by us, which breach remains uncured at the end of such 30 day period. There can be no assurance that ERBA Mannheim 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 MKT (formerly known as the NYSE Amex, and prior to that the American Stock Exchange) since March 15, 2001. Because ERBA Mannheim beneficially owns, directly or indirectly, approximately 82.4% of the issued and outstanding shares of our common stock, we have a limited non-affiliate market capitalization. As a result, our common stock has a limited trading volume, which 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 the line of credit or the investment contemplated by the stock purchase agreement, issuing debt or equity securities, incurring indebtedness or curtailing or reducing our operations;
- the remaining transactions contemplated by the investment under the stock purchase agreement may not be consummated on the contemplated terms, in the time frame anticipated, or at all;
- the net proceeds of the investment contemplated by the stock purchase agreement may not provide adequate cash resources to fund our operations or liquidity needs for the reasonably foreseeable future;
- our ability to achieve or sustain profitability from our operations or otherwise secure funds to provide the basis for our long-term liquidity;
- our broad discretion in our use of the net proceeds from the investment contemplated by the stock purchase agreement;
- the warrants may not be exercised, in whole or in part;
- the decision to exercise the warrants will be made by ERBA Mannheim based upon considerations it deems appropriate, which may include, among other things, the future market price of our common stock, which is subject to volatility and a number of other factors, many of which are beyond our control, and, when making any such decision to exercise the warrants, ERBA Mannheim's interests may conflict with our interests;
- our ability to pay when due the principal and interest on our outstanding indebtedness under the line of credit;
- our ability to operate our business under the restrictions imposed by the positive and negative covenants to which we are subject under the loan agreement in connection with the line of credit;
- our ability to remediate our material weakness relating to our internal controls over financial reporting;
- our ability to timely cure our non-compliance with the continued listing standards of the NYSE MKT within the anticipated timeframe or at all, which, if not timely cured, could result in our common stock being delisted from the NYSE MKT;
- if we timely cure our non-compliance with the continued listing standards of the NYSE MKT, our ability to maintain compliance with the continued listing standards of the NYSE MKT, the failure of which could result in our common stock being delisted from the NYSE MKT;
- 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 successfully market the Ds5 instrument system for diabetes testing;
- our ability to successfully market the Ds360 instrument system for diabetes testing;
- our ability to successfully market the D3 instrument system for hematology testing;
- our ability to successfully market the 2280 instrument system for hematology testing;
- our ability to successfully market generic clinical chemistry reagents;
- 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, including, without limitation, our ability to integrate the businesses commonly known as Drew Scientific and JAS Diagnostics;
- acquisitions of business and products, and the integration of acquired businesses and products, may disrupt our business, distract our management and may not proceed as planned, including, without limitation, our acquisition of and our ability to integrate the businesses commonly known as Drew Scientific and JAS Diagnostics;
- our ability to achieve economies of scale or to maximize the utilization of our assets and facilities, after any integration of the businesses commonly known as Drew Scientific and JAS Diagnostics into our legacy operations;
- our ability to enter into and exploit the diabetes market;

- our ability to leverage the marketing and distribution infrastructure that ERBA Mannheim and its affiliates have established around the world;
- the timing of the closing of our Drew Scientific facility in Dallas, Texas;
- 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, particularly in Italy, 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 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 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;
- the success of the move of our headquarters from our Miami, Florida facility to our Miami Lakes, Florida facility;
- 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 ERBA Mannheim, 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 Mannheim;
- conflicts of interest with ERBA Mannheim and its affiliates, including Suresh Vazirani, Sanjiv Suri 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 Lakes, Florida. Our corporate headquarters share facilities with Drew Scientific and JAS Diagnostics.

Diamedix owns approximately 52,000 square feet of buildings at its facility in Miami, Florida. From this facility, Diamedix conducts research and development of in vitro diagnostic products and reagent kit manufacturing. Delta leases approximately 34,000 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.

Drew Scientific leases approximately 1,100 square feet of commercial space in Waterbury, Connecticut and approximately 20,000 square feet of commercial space in Dallas, Texas. From its Connecticut location, Drew Scientific manages technical services and, from its Texas location, it services equipment. In May 2013, our management announced that it intends to close the Dallas, Texas facility effective in late September 2013. JAS Diagnostics leases approximately 20,000 square feet of commercial space in Miami Lakes, Florida, where it manufactures reagents for hematology and clinical chemistry. Through December 31, 2012, Drew Scientific Limited Co. leased approximately 2,500 square feet of commercial space in Borrow-in-Furness, United Kingdom, where it manufactured reagents for diabetes testing. We closed the United Kingdom facility in late March 2013.

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. MINE SAFETY DISCLOSURES

Not applicable.

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 MKT (formerly known as the NYSE AMEX) and trades under the symbol "ERB."

As of the close of business on June 7, 2013, there were approximately 107 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 2012 and 2011, as reported by the NYSE MKT:

2012	High	Low
Fourth Quarter	$0.99	$0.48
Third Quarter	0.90	0.29
Second Quarter	0.72	0.37
First Quarter	0.75	0.41
2011	**High**	**Low**
Fourth Quarter	$0.64	$0.40
Third Quarter	0.99	0.56
Second Quarter	1.23	0.51
First Quarter	1.80	0.55

We did not declare or pay cash dividends on our common stock during 2012 or 2011, 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 42 to 71 of this Annual Report on Form 10-K.

OVERVIEW

We are the parent corporation of the following five subsidiaries:

- Delta Biologicals, S.r.l.;
- Diamedix Corporation;
- Drew Scientific, Inc.;
- ImmunoVision, Inc.; and
- JAS Diagnostics, 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, infectious diseases, clinical chemistry, hematology and diabetes testing. 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, ImmunoVision, Drew Scientific and JAS Diagnostics, our subsidiaries located in the United States and corporate operations. Our other segment — the European region — contains Delta Biologicals, our subsidiary located in Italy. The operations of Drew Scientific in the United Kingdom are not material to our consolidated operations for the year ended December 31, 2012.

ACQUISITION OF DREW SCIENTIFIC, INC.

On October 3, 2012, we acquired all of the issued and outstanding shares of capital stock of Drew Scientific from a subsidiary of Escalon Medical Corp. pursuant to a Stock Purchase Agreement between, among others, us and Escalon. Included in the acquired businesses were Drew Scientific's wholly-owned subsidiaries — JAS Diagnostics, Inc. and Drew Scientific Limited Co. For further details of this acquisition, see also Note 4, *Acquisition of Drew Scientific, Inc.*, to the consolidated financial statements.

The acquired businesses, collectively referred to as Drew Scientific, were acquired with the purpose of integrating Drew Scientific's manufacturing and distribution capabilities with our legacy operations in an effort to achieve economies of scale and maximize the utilization of our assets and facilities. We paid $6,500,000 for all of the issued and outstanding shares of capital stock of Drew Scientific, which purchase price was funded through the purchase by ERBA Mannheim from us of 8,666,667 shares of our common stock at a purchase price of $0.75 per share, for an aggregate purchase price of $6,500,000.

Drew Scientific operates in the healthcare industry as a diagnostics company specializing in the design, manufacture and distribution of instruments for blood cell counting and blood analysis, focused on providing instrumentation and consumables for physician offices and veterinary office laboratories. Certain Drew Scientific subsidiaries also supply the reagent and other consumable materials needed to operate the instruments and manufacture a broad range of liquid stable, diagnostics chemistry reagents used in diabetes testing. Drew Scientific Limited Co. operated a similar business in the United Kingdom.

Drew Scientific, Inc. is a diagnostics company specializing in the design, manufacture and distribution of instruments for blood cell counting and blood analysis. Drew Scientific is focused on providing instrumentation and consumables for the physician office and veterinary office laboratories. Drew Scientific also supplies the reagent and other consumable materials needed to operate the instruments. JAS Diagnostics, Inc. specializes in the manufacture of a broad range of liquid stable, diagnostics chemistry reagents used for in

vitro diagnostics testing. Many of these reagents are single vial stable, which we believe offer ease of use, increased speed of results and extended on-board stability. JAS Diagnostics' reagents are sold through distributors and directly to end users customers — physician, reference, hospital and veterinary diagnostic testing laboratories.

Prior to the October 3, 2012 acquisition date, our management decided to cease the operations of Drew Scientific and its subsidiaries at their facilities in both Dallas, Texas and the United Kingdom. As a result, we have accrued on the opening balance sheet as of October 3, 2012 estimated plant closing costs, including lease buy-out and severance costs, of $160,000 and $118,000, respectively. Regarding the Dallas, Texas facility, in May 2013, the Company's management announced that the closing would be effective in late September 2013. With respect to the United Kingdom facility, the closing was effective in late March 2013.

Included in the accompanying consolidated statement of operations and comprehensive loss are Drew Scientific revenues of approximately $3,391,000 and net loss of approximately $238,000 since October 3, 2012, the acquisition date. Unaudited pro forma information for the years ended December 31, 2012 and 2011, as though we had completed the acquisition of Drew Scientific as of the beginning of each period, would be approximately as follows; revenues of $29,264,000 and $30,148,000; net loss of $1,368,000 and $5,791,000; and net loss per share of $0.04 and $0.16. This unaudited pro forma financial information is presented for informational purposes only. The unaudited pro forma financial information may not necessarily reflect our future results of operations or what the results of operations would have been had we owned and operated Drew Scientific as of the beginning of the periods presented.

MAJORITY STOCKHOLDER

On July 25, 2005, IVAX Corporation, 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 Corporation to be merged into a wholly-owned subsidiary of Teva. On January 26, 2006, the merger was consummated and IVAX Corporation became a wholly-owned subsidiary of Teva. As a result of the merger, Teva, indirectly through its wholly-owned IVAX Corporation subsidiary, owned approximately 72.3% of the then 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 then outstanding shares of our common stock then owned by Teva, indirectly through its wholly-owned IVAX Corporation subsidiary. 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 Mannheim, 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 then 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, the consummation of the various transactions contemplated by the investment made by ERBA Mannheim pursuant to that certain Stock Purchase Agreement, as further described below, including ERBA Mannheim's purchase from us, and our issuance to ERBA Mannheim, of an aggregate of 15,333,334 shares of our common stock, and ERBA Mannheim's exercise, in part, of the Warrant, as further described below, for 600,000 shares of our common stock, ERBA Mannheim now beneficially owns, directly or indirectly, approximately 82.4% of the outstanding shares of our common stock.

RESULTS OF OPERATIONS

YEAR ENDED DECEMBER 31, 2012 COMPARED TO YEAR ENDED DECEMBER 31, 2011

OVERVIEW

Net loss totaled $1,553,000 for the year ended December 30, 2012 compared to a net loss of $3,297,000 for the year ended December 30, 2011. Operating loss was $1,203,000 in 2012 compared to an operating loss of $3,228,000 in 2011. The decrease in operating loss in 2012 compared to 2011 resulted primarily from decreases in operating expenses, partially offset by the operating loss of $221,000 for Drew Scientific since the October 3, 2012 acquisition date. The decrease in net loss in 2012 compared to 2011 resulted primarily from decreases in operating expenses, partially offset by the net loss of $238,000 for Drew Scientific since the October 3, 2012 acquisition date.

Net revenues increased by $2,589,000 to $19,349,000 in 2012 from $16,760,000 in 2011. This net increase was attributed to the post-acquisition net revenues of $3,391,000 for Drew Scientific offset by other factors from recurring operations resulting in a decrease of $802,000. This decrease of $802,000 consisted of a decrease in net revenues from domestic operations of $581,000, to $10,926,000 in 2012 from $11,507,000 in 2011, and a decrease in net revenues from European operations of $221,000, including the effect of exchange rate fluctuations of the United States dollar relative to the Euro, to $5,032,000 in 2012 from $5,253,000 in 2011.

Gross profit increased by $490,000 to $9,092,000 in 2012 from $8,602,000 in 2011. This net increase was attributed to the post-acquisition gross profit of $881,000 for Drew Scientific offset by other factors from recurring operations resulting in a decrease of $391,000. This decrease of $391,000 from recurring operations was primarily the result of lower domestic and European revenues.

Total operating expenses decreased by $1,535,000 to $10,295,000 in 2012 from $11,830,000 in 2011. This net decrease was attributed to factors from recurring operations resulting in a decrease of $2,637,000, which was partially offset by the post-acquisition expenses of $1,102,000 for Drew Scientific. This net decrease of $1,535,000 was a result of decreases in all three expense categories. Comparing 2012 to 2011, selling expenses decreased by $437,000, general and administrative expenses decreased by $769,000 and research and development expenses decreased by $329,000.

NET REVENUES AND GROSS PROFIT (YEARS ENDED DECEMBER 31)

The following table presents comparative net revenues and gross profit for our operations, including the operations for Drew Scientific since the October 3, 2012 date of acquisition (net revenues of $3,391,000, cost of sales of $2,510,000 and gross profit of $881,000).

	2012	2011	Increase (Decrease)
Net Revenues:			
Domestic	$14,317,000	$11,507,000	$2,810,000
European	5,032,000	5,253,000	(221,000)
Total	19,349,000	16,760,000	2,589,000
Cost of Sales	10,257,000	8,158,000	2,099,000
Gross Profit	$ 9,092,000	$ 8,602,000	$ 490,000
% of Total	47.0%	51.3%	

The net increase in revenues was attributed to the post-acquisition net revenues of $3,391,000 for Drew Scientific, a decrease of $581,000 in net revenues from our legacy domestic operations and a decrease of $221,000 in net revenues from European operations. Exchange rate differences resulting from the strength or weakness of the United States dollar against the Euro resulted in a decrease of approximately $442,000 in net revenues in 2012 as compared to 2011, as further discussed in "Currency Fluctuations" below. As measured in Euros, net revenues from European operations in 2012 decreased by Euro 32,000, or 0.8%, compared to 2011. The decrease in net revenues from European operations (as measured by the Euro) was mainly due to

contract research and development revenue partially offset by the declines in reagent sales in Italy and other international markets. The decrease in the legacy domestic net revenues of $581,000, or 5.0%, was principally due to a decline in sales to international customers, principally in Latin America and Japan, partially offset by an increase in reagent sales.

The net increase in gross profit was attributed to the post-acquisition gross profit of $881,000 for Drew Scientific offset by a decrease in gross profit of $391,000 for our recurring operations. Gross profit as a percentage of net revenues decreased from 51.3% in 2011 to 47.0% in 2012, resulting principally from the lower gross profit percentage of 26.0% for the operations of Drew Scientific partially offset by an increase in reagent sales, which have a higher gross profit margin than instrument sales.

OPERATING EXPENSES (YEARS ENDED DECEMBER 31)

The following table presents comparative operating expenses for us, including the amounts for Drew Scientific of $1,102,000 (selling expenses of $522,000, general and administrative expenses of $320,000 and research and development expenses of $260,000) since the October 3, 2012 date of acquisition. The percentages below are based on the net revenues in the above table.

	2012	% of Revenue	2011	% of Revenue	(Decrease)
Selling	$ 4,617,000	23.9%	$ 5,054,000	30.1%	$ (437,000)
General and Administrative	4,555,000	23.5%	5,324,000	31.8%	(769,000)
Research and Development	1,123,000	5.8%	1,452,000	8.7%	(329,000)
Total Operating Expenses	$10,295,000	53.2%	$11,830,000	70.6%	$(1,535,000)

The net decrease in total operating expenses was attributed to a decrease in expenses of $2,637,000 from $11,830,000 in 2011 to $9,193,000 in 2012 for our recurring operations, as a result of decreases in all three categories of expenses, which was partially offset by the post-acquisition expenses of $1,102,000 for Drew Scientific.

The net decrease of $437,000 in selling expenses in 2012 compared to 2011 was due to a decrease of $959,000 in our recurring operations, which was partially offset by the post-acquisition expenses of $522,000 for Drew Scientific. The decrease of $959,000 was due principally to open sales positions in the United States and, in Italy, reduction in workforce and lower commissions from lower sales in various commissionable categories.

The net decrease of $769,000 in general and administrative expenses was due to a decrease of $1,089,000 in our recurring operations, which was partially offset by the post-acquisition expenses of $320,000 for Drew Scientific. The decrease of $1,089,000 was due principally to reductions in workforce and building expenses in both the United States and Italy, partially offset by an increase in the provision for doubtful accounts in Italy.

The net decrease of $329,000 in research and development expenses was due to a decrease of $589,000 in our recurring operations, which was partially offset by the post-acquisition expenses of $260,000 for Drew Scientific. The decrease of $589,000 was due principally to the reduction of research and development activities in the United States and the funding by ERBA Mannheim (beginning in December 2011) of the research and development efforts in Italy, for which the relevant expenses are now included in cost of sales. See also Note 14, *Related Party Transactions*, to the consolidated financial statements.

LOSS FROM OPERATIONS

Including the operations of Drew Scientific since the acquisition date, loss from operations totaled $1,203,000 in 2012 as compared to an operating loss of $3,228,000 in 2011, primarily due to the net reduction in operating expenses as described above. Loss from operations in 2012 was composed of an operating loss of $221,000 for Drew Scientific, an operating loss of $600,000 from recurring domestic operations and an operating loss of $382,000 from our European operations. Loss from operations in 2011 was composed of a $1,371,000 loss from domestic operations and a $1,857,000 loss from European operations. Domestic operations include corporate expenditures, including costs required to maintain our status as a public company.

OTHER INCOME (EXPENSE), NET

Other income (expense) totaled a net expense of $228,000 in 2012 as compared to a net expense of $361,000 in 2011. The 2012 amounts consist of foreign currency translation losses of $56,000, net interest expense of $40,000, expenses of $211,000 related to the acquisition of Drew Scientific and net other income of $79,000. The 2011 balance consists of foreign currency translation losses of $168,000, interest expense of $22,000 and net other expenses of $171,000.

INCOME TAX PROVISION

We recorded recurring income tax provisions of $122,000 for 2012 and a net benefit of $292,000 for 2011. The current portion of our tax provisions in both years relates to Italian local income taxes based upon applicable statutory rates effective in Italy. In addition, the domestic provision of $10,500 for 2012 represents an estimated charge for expected future expenditure to resolve a state tax matter. The deferred tax provisions in these years relate to domestic tax deductible goodwill. No current tax benefit was recorded during the two years on our losses because we had a full valuation allowance against the net deferred income tax assets.

During 2011, our wholly-owned subsidiary in Italy, Delta Biologicals, S.r.l., eliminated the balance of its intercompany loan of approximately $2,680,000 due to us, as a result of converting the loan to capital (equity). We had accrued for a potential withholding tax that would have been due upon payment of the interest on the loan. With the conversion of the balance to equity, approximately $406,000 of withholding tax liability was relieved during 2011, as the accrued interest will not be paid and therefore no withholding tax should be accrued. This reversal of the tax liability was recorded in 2011 as a one-time credit to income tax expense in the accompanying consolidated financial statements.

See also Note 8, *Income Taxes*, to the consolidated financial statements regarding other tax matters.

NET LOSS

Including the net loss of $238,000 for Drew Scientific since the acquisition date, we generated a net loss of $1,553,000 in 2012 as compared to a net loss of $3,297,000 in 2011. Basic and diluted net loss per common share was $0.04 in 2012 as compared to $0.11 in 2011. The net loss for both years resulted from the various factors discussed above.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2012, our working capital was $9,834,000 compared to $8,631,000 at December 31, 2011. Cash and cash equivalents totaled $4,126,000 at December 31, 2012 and $3,653,000 at December 31, 2011. As more fully described in Note 4, *Acquisition of Drew Scientific, Inc.*, to the consolidated financial statements, during the year ended December 31, 2012, ERBA Mannheim paid $6,500,000 to us in consideration of the issuance, on October 3, 2012, of 8,666,667 shares of our common stock, which funds were used by us to fund the acquisition, on October 3, 2012, of Drew Scientific and its wholly-owned subsidiaries.

Operating activities

Net cash flows of $202,000 were provided by operating activities during the year ended December 31, 2012 as compared to $2,850,000 that was used in operating activities during the year ended December 30, 2011.

Cash provided by operating activities of $202,000 during 2012 was the result of the net loss of $1,553,000, offset by changes in operating assets and liabilities of $320,000 and non-cash items of $1,435,000. The non-cash items include principally depreciation, amortization of intangible assets, adjustments to both the allowances for doubtful accounts and inventory obsolescence and deferred income taxes. Cash provided by changes in operating assets and liabilities was due to changes in accounts receivable, inventories, other current assets, accounts payable and accrued expenses and other long-term liabilities.

Cash used in operating activities of $2,850,000 during 2011 was the result of the net loss of $3,297,000 and changes in operating assets and liabilities of $928,000, partially offset by non-cash items of $1,375,000. The non-cash items include principally depreciation and amortization, adjustments to both the allowances for doubtful accounts and inventory obsolescence and deferred income taxes.

Investing activities

As noted above and throughout this Annual Report on Form 10-K, we acquired Drew Scientific on October 3, 2012. As discussed in Note 4, *Acquisition of Drew Scientific, Inc.*, to the consolidated financial statements, the fair value of assets acquired aggregated $8,261,000, including accounts receivable of $1,211,000, inventory of $2,093,000, identifiable intangible assets of $1,848,000, other assets of $485,000 and goodwill of $2,624,000. The fair value of liabilities assumed aggregated $1,761,000.

Net cash of $6,622,000 and $469,000 was used in investing activities during 2012 and 2011, respectively. The cash flows relating to investing activities in 2012 were principally for the acquisition of Drew Scientific ($6,453,000, net of cash acquired of $47,000), capital expenditures of $105,000, acquisition of equipment on lease of $77,000, offset by cash released from restricted deposits of $13,000. The cash flows relating to investing activities in 2011 were principally for capital expenditures (including the upgrade of our information technology infrastructure in the United States) and acquisition of equipment on lease, offset by cash released from restricted deposits.

Financing activities

Financing activities during 2012 reflect the receipt of proceeds of $6,950,000 from the issuances of common stock, net proceeds of $86,000 under the Line of Credit and capital lease payments of $79,000. In April 2012, we received $450,000 from ERBA Mannheim in connection with its partial exercise of the Warrant. In September 2012, we received $6,500,000 from ERBA Mannheim as an advance in connection with our issuance in October 2012 of shares to it under the Stock Purchase Agreement, as amended, between us and ERBA Mannheim. We used the proceeds from this advance to acquire, on October 3, 2012, Drew Scientific and its wholly-owned subsidiaries.

Financing activities during 2011 reflect the consummation of two significant financing arrangements — the Line of Credit under the Loan Agreement, under which we drew down $737,000 as of December 31, 2011, and the investment by ERBA Mannheim under the Stock Purchase Agreement, resulting in our receipt of net proceeds (after expenses of $400,000 related to the offering) of $4,600,000. In 2011, we also incurred capital lease payments of $72,000 and bank financing costs of $101,000.

Other matters

Liquidity is expected to be sufficient for the next twelve months from the combination of the existing cash and cash equivalents at December 31, 2012, and the investment that ERBA Mannheim has agreed to make under the Stock Purchase Agreement, including the Warrant, as described throughout this Annual Report on Form 10-K.

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 $1,123,000 during the year ended December 31, 2012 and $1,452,000 for the year ended December 31, 2011. In the fourth quarter of 2011, Delta Biologicals entered into a contract research and development agreement, as amended, with ERBA Mannheim for a total of Euro 754,700 (equivalent to approximately $1,003,000). Totals of Euro 133,000 (equivalent to approximately $186,000) and Euro 621,700 (equivalent to approximately $799,000) were invoiced under the contract in the fourth quarter of 2011 and the year ended December 31, 2012, respectively. 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, which 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 connection with our evaluation of our operating results, financial condition and cash position, and specifically considering our results of operations and cash utilization during 2012, we continue to implement measures expected to improve future cash flow. To this end, we expect operating results to continue to improve from the operating results achieved during 2012 based principally upon increases in revenue as a result of new channels of distribution in the United States and international markets.

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.

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. For the long-term, we intend to utilize principally existing cash and cash equivalents, proceeds we expect to receive from ERBA Mannheim pursuant to the investment contemplated by the Stock Purchase Agreement, including the Warrant, 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.

As of December 31, 2012, 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.

The critical accounting policies discussed below 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.

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.

We recognize milestone payments when earned, as evidenced by written acknowledgment from the collaborator, provided that the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, the milestone represents the culmination of an earnings process, the milestone payment is non-refundable and our past research and development services, as well as our ongoing commitment to provide research and development services under the collaboration, are charged at fees that are comparable to the fees that we customarily charge for similar research and development services.

During the year ended December 31, 2011, one of our subsidiaries entered into a contract research and development agreement with ERBA Mannheim, as amended. Expenses incurred pursuant to that contract are included in cost of sales as the related revenues are recorded from the achievement of milestones.

ALLOWANCE FOR DOUBTFUL ACCOUNTS

We grant credit without collateral to our customers based on our 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 our periodic credit evaluations of our customers' financial condition. 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.

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 as of December 31, 2012 included components for current or future versions of products and instrumentation.

Our inventory balance as of December 31, 2012 and December 31, 2011 included approximately $100,000 of inventory relating to our hepatitis product, substantially all of which has a shelf life exceeding five years, for which we obtained "CE Marking" approval in the European Union during 2011 and which we have begun marketing in certain markets. Inventory reserves were $816,000 and $419,000 as of December 31, 2012 and December 31, 2011, 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. 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 years 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 of 900,000 Euros upon the achievement of the enumerated performance objectives in prior years. During the year ended December 31, 2012, the balance of 100,000 Euro (equivalent to approximately $132,000) was offset against the accounts receivable owed to us from the Italian diagnostics company.

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" 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 obtained "CE Marking" during 2011, there remains a risk that we will not be able to market or 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 adversely impacted, then we may be required to record an additional impairment charge with respect to all or a portion of the remaining carrying value of $283,000.

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 year 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 years 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 our 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, 2012. 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 Mannheim of the approximately 72.33% of the then 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 $827,000 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 the years ended December 31, 2012 and 2011 were not impacted by these limitations.

See also Note 8, *Income Taxes*, to the consolidated financial statements regarding other tax matters.

RECENTLY ISSUED ACCOUNTING STANDARDS

Refer to Note 3, *Summary of Significant Accounting Policies*, under the heading, *Recently Issued Accounting Standards*, to the consolidated financial statements regarding recently issued accounting standards applicable to us.

CURRENCY FLUCTUATIONS

For the years December 31, 2012 and 2011, approximately 26.7% and 32.9%, 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 relationship of the United States dollar against the Euro resulted in a decrease of approximately $442,000 in net revenues for the year ended December 31, 2012 as compared to the year ended December 31, 2011. 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, 2012 and 2011, none of our subsidiaries was 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

Refer to Note 8, *Income Taxes*, to the consolidated financial statements and the *Income Taxes* section of Critical Accounting Policies included in this Annual Report on Form 10-K regarding income tax matters.

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

ERBA Diagnostics, Inc. and Subsidiaries
Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders
ERBA Diagnostics, Inc.

We have audited the accompanying consolidated balance sheet of ERBA Diagnostics, Inc. (a Delaware corporation) and its subsidiaries (collectively, the "Company") as of December 31, 2012, and the related consolidated statements of operations and comprehensive loss, shareholders' equity, and cash flows for the year then ended. The Company's management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated 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 consolidated 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 consolidated 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 consolidated financial position of ERBA Diagnostics, Inc. and its subsidiaries as of December 31, 2012, and the results of their operations and their cash flows for the year then ended in conformity with U.S. generally accepted accounting principles.

/s/ Mayer Hoffman McCann P.C.

Miami, Florida
June 14, 2013

Report of Independent Registered Public Accounting Firm

Board of Directors and Shareholders
ERBA Diagnostics, Inc.

We have audited the accompanying consolidated balance sheet of ERBA Diagnostics, Inc. (a Delaware corporation) and subsidiaries as of December 31, 2011, and the related consolidated statements of operations and comprehensive loss, shareholders' equity and cash flows for the year then ended. 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 consolidated financial position of ERBA Diagnostics, Inc. and subsidiaries as of December 31, 2011, 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.

/s/ Grant Thornton LLP

Miami, Florida
April 16, 2012

ERBA Diagnostics, Inc. and Subsidiaries

Consolidated Balance Sheets
December 31, 2012 and 2011

	2012	2011
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 4,125,818	$ 3,653,244
Accounts receivable, net	6,369,165	5,950,621
Inventories, net	5,838,150	3,830,295
Other current assets	219,636	231,992
Total current assets	16,552,769	13,666,152
PROPERTY, PLANT AND EQUIPMENT:		
Land	352,957	352,957
Buildings and improvements	3,068,607	3,062,569
Machinery and equipment	3,731,139	3,264,419
Furniture and fixtures	2,050,241	1,997,371
	9,202,944	8,677,316
Less accumulated depreciation	(7,605,984)	(7,220,376)
	1,596,960	1,456,940
OTHER ASSETS:		
Intangible assets, net	1,812,048	—
Goodwill	3,494,619	870,290
Equipment on lease, net	585,321	674,504
Product license	282,936	282,936
Restricted deposits	148,040	127,859
Other assets	81,075	128,203
	6,404,039	2,083,792
Total assets	$ 24,553,768	$ 17,206,884
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 3,064,516	$ 2,345,838
Capital lease obligation, current	21,947	79,186
Accrued license payable	—	129,490
Revolving line of credit	822,635	736,566
Other accrued expenses	2,809,447	1,744,221
Total current liabilities	6,718,545	5,035,301
OTHER LONG-TERM LIABILITIES:		
Capital lease obligation, noncurrent	—	21,287
Deferred tax liabilities	509,365	428,676
Other long-term liabilities	993,980	994,348
Total other long-term liabilities	1,503,345	1,444,311
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Common stock, par value $0.01, authorized 100,000,000 shares, issued and outstanding 43,658,221 in 2012 and 34,391,554 in 2011	436,582	343,915
Additional paid-in capital	52,947,370	46,035,037
Accumulated deficit	(36,537,171)	(34,983,815)
Accumulated other comprehensive loss	(514,903)	(667,865)
Total shareholders' equity	16,331,878	10,727,272
Total liabilities and shareholders' equity	$ 24,553,768	$ 17,206,884

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

ERBA Diagnostics, Inc. and Subsidiaries

Consolidated Statements of Operations and Comprehensive Loss
For the Years Ended December 31, 2012 and 2011

	2012	2011
NET REVENUE	$19,349,004	$16,759,773
COST OF SALES	10,257,367	8,158,463
Gross profit	9,091,637	8,601,310
OPERATING EXPENSES:		
Selling	4,616,684	5,054,179
General and administrative	4,555,577	5,323,908
Research and development	1,122,537	1,451,525
Total operating expenses	10,294,798	11,829,612
(Loss) from operations	(1,203,161)	(3,228,302)
OTHER INCOME (EXPENSE), NET:		
Interest income (expense)	(39,808)	(21,962)
(Unrealized loss) on foreign currency transactions	(55,793)	(167,919)
Acquisition expenses	(211,099)	—
Other income (expense), net	78,550	(171,150)
Total other income (expense), net	(228,150)	(361,031)
(Loss) before provision (credit) for income taxes	(1,431,311)	(3,589,333)
PROVISION (CREDIT) FOR INCOME TAXES	122,045	(291,990)
Net (loss)	(1,553,356)	(3,297,343)
OTHER COMPREHENSIVE INCOME (LOSS):		
Foreign currency translation adjustment	152,962	(55,005)
Total comprehensive (loss)	$(1,400,394)	$(3,352,348)
Net (loss) per share – basic and diluted	$ (0.04)	$ (0.11)
WEIGHTED AVERAGE SHARES OUTSTANDING:		
Basic and diluted	36,947,292	31,058,494

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

ERBA Diagnostics, Inc. and Subsidiaries

Consolidated Statements of Shareholders' Equity
For the Years Ended December 31, 2012 and 2011

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
	Shares	Amount				
Balances as of December 31, 2010	27,649,887	$276,498	$41,389,404	($ 31,686,472)	($ 612,860)	$ 9,366,570
Issuance of common stock	6,666,667	66,667	4,533,633	—	—	4,600,300
Exercise of stock options	75,000	750	36,750	—	—	37,500
Stock compensation expense	—	—	75,250	—	—	75,250
Net (loss)	—	—	—	(3,297,343)	—	(3,297,343)
Foreign currency translation adjustment	—	—	—	—	(55,005)	(55,005)
Balances as of December 31, 2011	34,391,554	343,915	46,035,037	(34,983,815)	(667,865)	10,727,272
Issuance of common stock	9,266,667	92,667	6,857,333	—	—	6,950,000
Stock compensation expense	—	—	55,000	—	—	55,000
Net (loss)	—	—	—	(1,553,356)	—	(1,553,356)
Foreign currency translation adjustment	—	—	—	—	152,962	152,962
Balances as of December 31, 2012	43,658,221	$436,582	$52,947,370	($ 36,537,171)	($ 514,903)	$16,331,878

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

ERBA Diagnostics, Inc. and Subsidiaries

Consolidated Statements of Cash Flows
For the Years Ended December 31, 2012 and 2011

	2012	2011
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net (loss)	$(1,553,356)	$(3,297,343)
Adjustments to reconcile net (loss) to net cash provided by (used in) operating activities –		
Depreciation and amortization	726,214	736,380
Provision for doubtful accounts receivable	195,940	389,024
Provision for inventory obsolescence	377,486	111,748
Non-cash compensation	55,000	75,250
Deferred income tax provision	80,689	63,492
Changes in operating assets and liabilities, net of acquisition:		
Accounts receivable	783,020	(995,440)
Inventories	(179,128)	135,853
Other current assets	(126,026)	(85,626)
Accounts payable and accrued expenses	(116,953)	(22,225)
Other long-term liabilities	(41,180)	39,292
Net cash provided by (used in) operating activities	201,706	(2,849,595)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Capital expenditures	(105,233)	(244,077)
Acquisition of equipment on lease, net	(76,616)	(326,172)
Acquisition of Drew Scientific, Inc., net of cash acquired	(6,453,404)	—
Decrease in restricted deposits	12,797	100,821
Net cash (used in) investing activities	(6,622,456)	(469,428)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds of share offering	6,950,000	4,600,300
Proceeds from revolving line of credit	86,069	736,566
Bank financing related costs	—	(101,000)
Exercise of stock options	—	37,500
Capital lease payments	(78,929)	(71,965)
Net cash provided by financing activities	6,957,140	5,201,401
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(63,816)	(55,362)
NET INCREASE IN CASH AND CASH EQUIVALENTS	472,574	1,827,016
CASH AND CASH EQUIVALENTS, beginning of year	3,653,244	1,826,228
CASH AND CASH EQUIVALENTS, end of year	$ 4,125,818	$ 3,653,244
SUPPLEMENTAL DISCLOSURES:		
Income taxes paid	$ 8,836	$ 50,353
Interest paid	$ 39,911	$ 30,186
SUPPLEMENTAL DISCLOSURE OF NONCASH INVESTING ACTIVITIES: Refer to Note 4		

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

1 ORGANIZATION AND OPERATIONS

As approved by the Company's stockholders at the Company's Annual Meeting of Stockholders held on June 15, 2012, and as previously approved by the Company's Board of Directors, the Company's name was changed from IVAX Diagnostics, Inc. to ERBA Diagnostics, Inc. ("ERBA Diagnostics" or the "Company"). 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 1, 2010, ERBA Diagnostics Mannheim GmbH, an in vitro diagnostics company headquartered in Germany ("ERBA Mannheim"), 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 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, the consummation of the various transactions contemplated by the investment made by ERBA Mannheim pursuant to that certain Stock Purchase Agreement, as further described below, including ERBA Mannheim's purchase from the Company, and the Company's issuance to ERBA Mannheim, of an aggregate of 15,333,334 shares of the Company's common stock, and ERBA Mannheim's exercise, in part, of the Warrant, as further described below, for 600,000 shares of the Company's common stock, ERBA Mannheim now beneficially owns, directly or indirectly, approximately 82.4% of the outstanding shares of the Company's common stock.

2 LIQUIDITY

The Company incurred a net loss of $1,553,356 during the year ended December 31, 2012 and a net loss of $3,297,343 during the year ended December 31, 2011 and had cash provided by (used in) operations of $201,706 and ($2,849,595) for those respective years.

The Company has implemented certain initiatives and has significantly decreased operating expenses to improve operating results. The Company expects operating results to continue to improve upon increases in revenue as a result of the commercial launch of the Mago® 4S in the United States during 2011 and anticipated increases in the United States and international revenue from new channels of distribution. In addition, the acquisition of Drew Scientific, Inc. and its subsidiaries has expanded the Company's product base and potential available markets; see also Note 4, *Acquisition of Drew Scientific, Inc.* Management of the Company believes that it has sufficient resources to enable its continual existence as a going concern.

As discussed in Note 14, *Related Party Transactions*, the Company entered into a Stock Purchase Agreement with ERBA Mannheim on April 8, 2011. The Company and ERBA Mannheim modified the Stock Purchase Agreement such that the additional shares of the Company's common stock will only be issued on the date that is 60 days after the date on which a majority of the independent directors on the Company's Board of Directors determines by vote or written consent that such additional transaction shall occur and causes notice thereof to be delivered to ERBA Mannheim. On April 16, 2012, ERBA Mannheim exercised, in part, the Warrant by paying an aggregate exercise price of $450,000 to the Company and, in connection therewith, the Company issued to ERBA Mannheim 600,000 shares of the Company's common stock. On October 3, 2012, ERBA Mannheim acquired from the Company 8,666,667 shares of the Company's common stock at a purchase price of $0.75 per share (total proceeds of $6,500,000) to finance the acquisition of Drew Scientific, Inc. ("Drew Scientific"). See also Note 4, *Acquisition of Drew Scientific, Inc.*, regarding this transaction.

As discussed in Note 15, *Revolving Line of Credit*, on June 10, 2011, Diamedix Corporation ("Diamedix"), a wholly-owned subsidiary of the Company, entered into a loan agreement with City National Bank of Florida, which provided for a secured, revolving credit facility of up to $975,000. As discussed in Note 16, *Subsequent Events*, on March 1, 2013, the Company closed down the previously existing line of credit from City National Bank of Florida and entered into a new loan agreement with Citibank, N.A., which provides for a secured, revolving credit facility of up to $2,000,000.

3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The accompanying consolidated financial statements are presented in accordance with U.S. Generally Accepted Accounting Principles ("GAAP") and include the accounts of ERBA Diagnostics, Inc. and its wholly-owned subsidiaries Diamedix, ImmunoVision, Inc. ("ImmunoVision") and Delta Biologicals, S.r.l. ("Delta Biologicals") and, from and after the acquisition date of October 3, 2012, Drew Scientific, Inc. and its subsidiaries (as more fully described in Note 4, *Acquisition of Drew Scientific, Inc.*). All significant intra-entity balances and transactions have been eliminated in consolidation.

Reclassifications

Certain amounts in the prior year's consolidated financial statements have been reclassified to conform to the current year's presentation.

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 consolidated 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, stock based compensation, the computation of fair-value measurements related to the acquisition of Drew Scientific and its subsidiaries, the realization of long-lived assets and contingencies and litigation.

Cash and Cash Equivalents

The Company considers certain short-term investments in money market accounts with original maturities of three months or less to be cash equivalents.

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.

3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – (continued)

The allowance for doubtful accounts was $810,718 and $716,599 as of December 31, 2012 and 2011, respectively, and activity for the years then ended was as follows:

	2012	2011
Balance as of January 1	$ 716,599	$399,376
Provision	440,991	389,024
Write-offs	(361,229)	(76,685)
Effects of changes in foreign exchange rates	14,357	4,884
Balance as of December 31	$ 810,718	$716,599

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 as of December 31, 2012 and 2011:

	2012	2011
Raw materials	$1,712,199	$ 716,268
Work-in-process	664,880	717,390
Finished goods	3,461,071	2,396,637
Total inventories, net	$5,838,150	$3,830,295

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 times includes components for current or future versions of products and instrumentation. Inventory reserves were $816,000 and $419,000 as of December 31, 2012 and December 31, 2011, respectively.

The Company's inventory balance as of December 31, 2012 and 2011 included approximately $100,000 of inventory relating to the Company's hepatitis product, substantially all of which has a shelf life exceeding five years, for which regulatory approval was received in 2011 and which the Company began marketing in 2013.

3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – (continued)

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 $326,917 and $405,080 during the years ended December 31, 2012 and 2011, 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 Note 3, *Summary of Significant Accounting Policies*, below under the heading *Revenue Recognition*), less accumulated amortization, consists of the following as of December 31, 2012 and 2011:

	2012	2011
Equipment on lease, at cost	$6,666,122	$6,629,007
Less accumulated amortization	6,080,801	5,954,503
	$ 585,321	$ 674,504

Equipment on lease is typically amortized over three or five years. Amortization expense was $172,175 and $331,300 for the years ended December 31, 2012 and 2011, respectively.

Intangible Assets

Intangible assets relate to the acquisition of Drew Scientific (as more fully described in Note 4, *Acquisition of Drew Scientific, Inc.*) and consist of the following as of December 31, 2012:

	Estimated Useful Life (Years)	Gross Amount	Accumulated Amortization	Net Amount
Customer relationships	4.8	$1,026,532	$53,096	$ 973,436
Trademarks/tradenames	10.0	512,701	12,817	499,884
Patents	7.0	309,057	9,972	299,085
Lease rights	2.0	47,140	7,497	39,643
		$1,895,430	$83,382	$1,812,048

3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – (continued)

Amortization expense is computed principally on a straight-line basis and for the next five years approximates:

Years Ending December 31,	
2013	$ 328,000
2014	324,000
2015	306,000
2016	295,000
2017	208,000
	$1,461,000

For the period since October 3, 2012 through December 31, 2012, the Company has recorded total amortization of $83,382 with respect to the intangible assets acquired.

Long Lived Assets, Including Goodwill

Goodwill is attributed to the acquisitions of ImmunoVision and Drew Scientific and represents the excess of the cost over the fair value of nets assets acquired. 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 five years, long-term annual growth rates of 3% for both years and a discount rate of 20% for both years, no impairment was recorded for the years ended December 31, 2012 or 2011.

The Company reviews its long-lived assets for impairment, including intangible assets and fixed assets that are held and used in its operations, whenever events or changes in circumstances indicate that the carrying amount of the asset may not be recoverable. If such an event or change in circumstances occurs, then the Company will estimate the undiscounted future net cash flows expected to result from the use of the asset and its eventual disposition. If the sum of the undiscounted future cash flows is less than the carrying amount of the related assets, then the Company will recognize an impairment loss. Assets to be disposed of are reclassified as assets held for sale at the lower of their carrying amount or fair value less costs to sell. Write-downs to fair value less disposal costs are reported as a part of loss from operations.

The Company does not believe that there were any events or changes in circumstances which indicate that the carrying amounts of its long-lived assets may not be recoverable as of December 31, 2012 and 2011, respectively.

Restricted Deposits

Long-term restricted deposits of $148,040 and $127,859 as of December 31, 2012 and 2011, respectively, consist primarily of cash deposits required as part of the sales tender process with governmental customers in Italy and cash deposits made in connection with capital and operating leases.

Foreign Currency Translation

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

3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – (continued)

of operations and comprehensive loss 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" account in the consolidated statements of operations and comprehensive loss and consolidated statements of shareholders' equity.

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

Financial Instruments

The carrying amounts of cash and cash equivalents, 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, 2012 and 2011 were not significant.

The Company recognizes milestone payments when earned, as evidenced by written acknowledgment from the collaborator, provided that the milestone event is substantive and its achievability was not reasonably assured at the inception of the agreement, the milestone represents the culmination of an earnings process, the milestone payment is non-refundable and the Company's past research and development services, as well as the Company's ongoing commitment to provide research and development services under the collaboration, are charged at fees that are comparable to the fees that the Company customarily charges for similar research and development services.

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 operations and comprehensive loss 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. As described in Note 14, *Related Party Transactions*, during the year ended December 31, 2011, the Company entered into a contract research and development agreement with ERBA Mannheim. Expenses incurred pursuant to that contract are included in cost of sales as the related revenues are recorded from the achievement of milestones.

Foreign Currency Transactions

The Company has assets and liabilities held in foreign currency which are translated at period-end exchange rates, and revenues and expenses are translated at average rates prevailing during the period. Certain accounts receivable from customers are collected and certain accounts payable to vendors are payable in currencies other than the functional currencies of the Company. These amounts are adjusted to reflect period-end exchange rates. Unrealized losses on foreign currency transactions for the years ended December 31, 2012 and 2011 were $55,793 and $167,919, respectively.

3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – (continued)

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, 2012 and 2011.

As of December 31, 2012, the Company had stock-based employee compensation plans as described in Note 11, *Shareholders' Equity*. The Company recorded total compensation expense of $55,000 for the year ended December 31, 2012 and $75,250 for the year ended December 31, 2011.

Loss per Share

Basic loss per share excludes any dilution. It is based upon the weighted average number of shares of common stock outstanding during the period. Diluted loss per share reflects the potential dilution that would occur if securities or other contracts to issue common stock were exercised or converted into common stock. As of December 31, 2012 and 2011, 15,854,204 and 7,687,537 shares of common stock, respectively, underlying stock options and warrants were not included in computing diluted income per share because their effects would be anti-dilutive.

Fair Value Measurement

The Financial Accounting Standards Board's (the "FASB") Accounting Standards Codification Topic 820 ("ASC 820") defines fair value as the price that would be received to sell an asset or paid to transfer a liability in the principal market for the asset or liability or, in the absence of a principal market, the most advantageous market for the asset or liability, in an orderly transaction between market participants at the measurement date.

FASB ASC framework provides a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The hierarchy gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to unobservable inputs (Level 3 measurements).

The three levels of the fair value hierarchy under FASB ASC 820 are described below:

Level 1 Quoted market prices in active markets for identical assets or liabilities;

Level 2 Inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted market prices in markets that are not active or other inputs that are either directly or indirectly observable; and

Level 3 Unobservable inputs using estimates and assumptions developed by the Company, which reflect those that a market participant would use.

3 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES – (continued)

The asset or liability's fair value measurement level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Valuation techniques used need to maximize the use of the observable inputs and minimize the use of unobservable inputs.

Recently Issued Accounting Standards

In December 2011, the FASB issued FASB Accounting Standards Update No. 2011-12 "Comprehensive Income: Deferral of the Effective Date for Amendments to the Presentation of Reclassifications of Items Out of Accumulated Other Comprehensive Income in Accounting Standards Guidance No. 2011-05" ("ASU 2011-12"). This guidance is a deferral of the effective date pertaining to reclassification adjustments out of accumulated other comprehensive income in ASU 2011-05. FASB is to going to reassess the costs and benefits of those provisions in ASU 2011-05 related to reclassifications out of accumulated other comprehensive income. Due to the time required to properly make such a reassessment and to evaluate alternative presentation formats, the FASB decided that it is necessary to reinstate the requirements for the presentation of reclassifications out of accumulated other comprehensive income that were in place before the issuance of ASU 2011-05. All other requirements in ASU 2011-05 are not affected by this guidance, including the requirement to report comprehensive income either in a single continuous financial statement or in two separate but consecutive financial statements. The Company implemented the new guidance effective January 1, 2011. The provisions of this guidance did not have a material impact on the Company's consolidated financial statements.

In July 2012, the FASB issued ASU 2012-02 "Intangibles — Goodwill and Other." This guidance relates to testing indefinite-lived assets for impairment and will give entities an option not to calculate annually the fair value of an indefinite-lived intangible asset if the entity determines that it is not more likely than not that the asset is impaired. This type of assessment based on qualitative factors is similar to the goodwill impairment testing in ASU 2011-08. The amendments are effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. These new requirements are not expected to have a material impact on the Company's consolidated financial statements.

In February 2013, the FASB issued ASU 2013-02 "Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income." This guidance requires an entity to report the effect of significant reclassifications out of accumulated other comprehensive income (loss) on the respective line items in net income (loss) if the amount being reclassified is required under US GAAP. For other amounts that are not required under US GAAP to be reclassified, in their entirety to net income in the same reporting period, an entity is required to cross-reference other disclosures required under US GAAP that provide additional detail about those amounts. The amendments are effective prospectively for reporting periods beginning after December 15, 2012. These new disclosure requirements are not expected to have a material impact on the Company's consolidated financial statements.

4 ACQUISITION OF DREW SCIENTIFIC, INC.

Summary of Transaction

On October 3, 2012, the Company acquired all of the issued and outstanding shares of capital stock of Drew Scientific from a subsidiary of Escalon Medical Corp. ("Escalon") pursuant to a Stock Purchase Agreement between, among others, the Company and Escalon.

The acquired businesses had been commonly known as the Escalon Clinical Diagnostics Business, which consists of Drew Scientific (located in Waterbury, Connecticut, and Dallas, Texas), and its wholly-owned subsidiaries JAS Diagnostics, Inc. ("JAS Diagnostics") (located in Miami Lakes, Florida), and Drew Scientific Limited Co. (previously located in Barrow-in-Furness, United Kingdom). This group of companies develops and sells A1c and Hematology diagnostic instruments, reagents and chemistries. Drew Scientific provides instrumentation and consumables for physician office, small hospital and veterinary research

4 ACQUISITION OF DREW SCIENTIFIC, INC. – (continued)

laboratories. Drew Scientific also supplies the reagent and other consumable materials needed to operate the instruments. JAS Diagnostics manufactures a broad range of chemical reagents used in in vitro diagnostics tests.

The purchase price paid by the Company for the all of the issued and outstanding shares of capital stock of Drew Scientific was $6,500,000, which was funded through the purchase, on October 3, 2012, by ERBA Mannheim from the Company of 8,666,667 shares of the Company's common stock at a purchase price of $0.75 per share, for an aggregate purchase price of $6,500,000, pursuant to the terms of the Stock Purchase Agreement, as amended, between ERBA Mannheim and the Company.

Accounting Treatment

The purchase method of accounting was applied for the Drew Scientific business combination. The purchase price of $6,500,000 was allocated to net tangible and intangible assets based on their estimated fair values as of October 3, 2012, the acquisition date. The fair values determined by the Company's management represent the prices that management believes would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants.

The purpose of the acquisition was to integrate Drew Scientific's manufacturing and distribution capabilities with the Company's operations in an effort to achieve economies of scale and maximize the utilization of the Company's assets and facilities. Assets acquired included certain intangible assets: customer relationships (to be amortized over 4.8 years), patents (to be amortized over a weighted average estimated useful life of approximately 7 years), and trademarks/tradenames (to be amortized over 10 years). The excess of the purchase price over the estimated fair values of the identifiable assets was recorded as goodwill primarily attributable to synergies expected to be gained from the integration of Drew Scientific into the Company's existing operations. Transaction costs of approximately $211,000 associated with this acquisition were expensed as incurred through the consolidated statement of operations and comprehensive loss for the year ended December 31, 2012.

Below is a summary of assets acquired and liabilities assumed (rounded):

Purchase price	$6,500,000
Fair value of assets acquired:	
Trade accounts receivable	1,211,000
Inventories	2,093,000
Prepaid and other current assets	140,000
Property, plant and equipment	312,000
Customer relationships	1,026,000
Trademarks/tradenames	513,000
Patents	309,000
Other non-current assets	33,000
Total fair value of assets acquired	5,637,000
Fair value of liabilities assumed:	
Accounts payable	592,000
Accrued expenses	844,000
Deferred revenue	325,000
Total fair value of liabilities assumed	1,761,000
Fair value of net assets acquired	3,876,000
Excess of purchase price over fair value of net assets acquired	$2,624,000

4 ACQUISITION OF DREW SCIENTIFIC, INC. – (continued)

Pursuant to the Stock Purchase Agreement between the Company and Escalon, the Company will execute an election under Internal Revenue Code Section 338(h)(10), on behalf of both the buyer(s) and seller(s) to treat the transaction as if it were a sale of assets for income tax purposes. The impact of this election allows the Company to step-up the basis of all acquired assets to fair market value in a fashion similar to the purchase accounting treatment described earlier for the financial accounting books of record.

Prior to the October 3, 2012 acquisition date, the Company's management decided to cease the operations of Drew Scientific Limited Co. located in the United Kingdom and Drew Scientific's Dallas, Texas facility. As a result, the Company has accrued on the opening balance sheet as of October 3, 2012 estimated plant closing costs, including lease buy-out and severance costs, of $160,000 and $118,000, respectively. Regarding the Dallas, Texas facility, in May 2013, the Company's management announced that the closing would be effective in late September 2013. With respect to the United Kingdom facility, the closing was effective in late March 2013.

Included in the accompanying consolidated statement of operations and comprehensive loss are Drew Scientific revenues of approximately $3,391,000 and net loss of approximately $238,000 since October 3, 2012, the acquisition date. Unaudited pro forma information for the years ended December 31, 2012 and 2011 of the Company as though the Company had completed the acquisition of Drew Scientific as of the beginning of each period would be approximately as follows, respectively: revenues of $29,264,000 and $30,148,000; net loss of $1,368,000 and $5,791,000; and net loss per share of $0.04 and $0.16. This unaudited pro forma financial information is presented for informational purposes only. The unaudited pro forma financial information may not necessarily reflect our future results of operations or what the results of operations would have been had the Company owned and operated Drew Scientific as of the beginning of the periods presented.

5 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 components of the carrying amount of goodwill as of December 31, 2012 and 2011 are as follows:

	As of December 31, 2012			As of December 31, 2011		
	Gross Carrying Amount	Accumulated Impairment	Net Book Value	Gross Carrying Amount	Accumulated Impairment	Net Book Value
ImmunoVision	$6,722,725	$(5,852,435)	$ 870,290	$6,722,725	$(5,852,435)	$870,290
JAS Diagnostics . . .	2,624,329	—	2,624,329	—	—	—
	$9,347,054	$(5,852,435)	$3,494,619	$6,722,725	$(5,852,435)	$870,290

6 PRODUCT LICENSE

In September 2004, the Company entered into a license agreement with an Italian diagnostics company to obtain a perpetual, worldwide, royalty-free license of product technology 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. During the year ended December 31, 2012, the balance of 100,000 Euro (equivalent to approximately $132,000) was offset against

6 PRODUCT LICENSE – (continued)

the accounts receivable owed to the Company from the Italian diagnostics company. In October 2011, the Company received "CE Marking" granting approval for the remaining products covered under the license agreement. Sales are expected to commence in 2013, at which time the Company will commence amortizing this balance.

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 five 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 five 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.

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 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.

A substantial portion of the Company's accounts receivable and revenues are derived from Delta Biologicals, the Company's subsidiary located in Italy, and its operations may be affected by the recent fiscal and debt crisis the Italian government is facing. As of December 31, 2012 and 2011, Delta Biologicals' accounts receivable, primarily due from Italian companies, were approximately $4,394,000 and $4,203,000, respectively. Amounts due from hospitals and laboratories controlled by the Italian government as of December 31, 2012 and 2011 were approximately $1,719,000 and $2,167,000, respectively, which accounted for approximately 27% and 36%, respectively, of the Company's consolidated net accounts receivable. Delta Biologicals recognized revenues during the years ended December 31, 2012 and 2011 in the amount of approximately $5,032,000 and $5,253,000, respectively, which represented approximately 26% and 31%, respectively, of the Company's consolidated net revenues.

In recent years, the Italian government has been experiencing severe fiscal and debt crises and a recession, including its increasingly uncertain ability to service its sovereign debt obligations, caused in part by the declining global markets and economic conditions. Accordingly, the Company is subject to certain economic, business and, in particular, credit risk if its customers located in Italy, which are hospitals or laboratories controlled by the Italian government, do not pay amounts owed to the Company, extend payment cycles even further or ask the Company to accept a lower payment amount than is owed to the Company. The Company's current allowances for doubtful accounts, although currently believed by management to be adequate, may not be adequate and the Company may be required to make additional allowances, which would adversely affect,

7 CONCENTRATION OF CREDIT RISK – (continued)

and could materially adversely affect, the Company's operating results in the period in which the determination or allowance is or was made. Any of these factors could materially and adversely affect the Company's business, prospects, operating results, financial condition and cash flows in the near term.

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. 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. From time to time cash balances exceed federally insured limits.

8 INCOME TAXES

The provision (benefit) for income taxes consists of the following for the years ended December 31, 2012 and 2011:

	2012	2011
Current:		
Domestic	$ 10,500	$(405,835)
Foreign	30,856	50,353
Deferred:		
Domestic	80,689	63,492
Total	$122,045	$(291,990)

The components of income (loss) before income taxes are as follows for the years ended December 31, 2012 and 2011:

	2012	2011
Domestic	$ (948,194)	$(1,719,692)
Foreign	(483,117)	(1,869,641)
Total	$(1,431,311)	$(3,589,333)

8 INCOME TAXES – (continued)

The significant components of the net deferred income tax asset balances are as follows as of December 31, 2012 and 2011:

	2012	2011
Current:		
Accounts receivable allowances	$ 275,413	$ 208,844
Reserves and accruals	384,065	240,752
Capitalized inventory costs	116,897	108,992
Other	608	—
Valuation allowance	(776,983)	(558,588)
Deferred income taxes	—	—
Long-term:		
Depreciation and basis differences on tangible and intangible assets	305,052	282,989
Stock based compensation	359,397	338,222
Other	20,433	34,916
Foreign net operating losses	931,213	1,824,091
Domestic net operating losses	7,411,884	6,530,150
Valuation allowance	(9,027,979)	(9,010,368)
Net deferred tax asset	$ —	$ —

The net deferred income tax liability balance consists of tax deductible goodwill of $509,365 and $428,676, as of December 31, 2012 and 2011, respectively.

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, 2012 and 2011, the Company had no net domestic deferred tax assets. As of December 31, 2012 and 2011, the Company had net deferred tax liabilities of $509,365 and $428,676, respectively, relating to tax deductible goodwill which is not expected to reverse in the foreseeable future. Additionally, as of December 31, 2012 and 2011, 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.

8 INCOME TAXES – (continued)

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 for the years ended December 31, 2012 and 2011:

	2012	2011
Provision (benefit) for income taxes at U.S. Federal statutory rate of 35%	$(500,959)	$(1,256,267)
Elimination of withholding tax on converted loan	—	(405,835)
Change in valuation allowance (excluding portion relating to stock options)	239,458	909,716
Foreign tax rate differential	293,028	399,740
Global permanent differences	90,518	60,656
Provision (benefit) for income taxes	$ 122,045	$ (291,990)

The Company's income tax provision or benefit for the years ended December 31, 2012 and 2011 was different from the amount computed on the loss before provision (benefit) for income taxes at the statutory rate of 35% primarily due to changes in the valuation allowance, foreign tax rate differential and global permanent differences.

The Company recorded a net income tax provision of $122,045 during the year ended December 31, 2012 and a benefit of $291,990 during 2011. During 2011, the Company's wholly-owned subsidiary in Italy, Delta Biologicals, eliminated the balance of its intercompany loan of approximately $2,680,000 due to the Company, as a result of converting the loan to capital (equity). The Company had accrued for a potential withholding tax that would have been due upon payment of the interest on the loan. With the conversion of the balance to equity, approximately $406,000 of withholding tax liability was relieved during 2011, as the accrued interest will not be paid and therefore no withholding tax should be accrued. This reversal of the tax liability was recorded in 2011 as a one-time credit to income tax expense in the accompanying consolidated financial statements.

Domestic net operating losses generated by the Company total $19,004,000 as of December 31, 2012 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. 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 Mannheim of the approximately 72.4% of the then 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 years ended December 31, 2012 or 2011.

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, 2012, the Company's Federal income tax returns for the years 2009 through 2012 and, with respect to foreign operations, the Italian income tax returns for 2008 through 2012 remain subject to examination. Although the Company's Federal income tax returns from 2002 through 2008 are not generally

8 INCOME TAXES – (continued)

open to examination, the Company remains subject to adjustments in these years to the extent of the net operating losses being carried forward from those years. No examinations are currently in progress with any taxing authorities.

Regarding the accounting for uncertainties in income taxes, the Company recognizes the financial statement liability 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 liability that has a greater than 50% likelihood of being realized upon ultimate settlement with the relevant tax authority. As of December 31, 2012 and 2011, the Company had no unrecognized tax liabilities. If uncertain tax positions had been recorded, then the Company would recognize interest and penalties related to uncertain tax positions in income tax expense.

In January 2013, ImmunoVision received three Notices of Final Assessments from the State of Arkansas Department of Finance & Administration for the tax years ended December 31, 2005, 2006 and 2008 for a total of $361,940 (including penalties and interest). Based on discussions with a representative of the Department, the Company was informed that the assessments related to unfiled tax returns for those years. The Company has located file copies of the returns for the years 2005 and 2006, which reflect zero taxable income and zero tax liability. Since the Company has been unable to locate a file copy of the 2008 return, a return for that year has been prepared resulting in total tax, penalties and interest of approximately $10,500. This amount is included in current domestic income taxes in the accompanying consolidated statement of operations and comprehensive loss.

9 EMPLOYEE BENEFIT PLANS

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 $112,970 and $72,728 were expensed during the years ended December 31, 2012 and 2011, respectively.

Drew Scientific adopted a 401(k) retirement plan for Drew Scientific's United States employees. Employer contributions are discretionary; no employer contributions have been made to the 401(k) retirement plan since Drew Scientific was acquired by Escalon on July 23, 2004. This plan has continued subsequent to October 3, 2012, the date of the acquisition of Drew Scientific by the Company; subsequent to December 31, 2012, this plan was merged into the Company's 401(k) employee savings plan.

Drew Scientific also has a defined contribution retirement plan. This plan has continued subsequent to October 3, 2012 and is available only to Drew Scientific's United Kingdom employees. Employer contributions since the date of acquisition through December 31, 2012 were not material; the plan was terminated in February 2013 as part of the closure of the United Kingdom facility.

10 ACCRUED EXPENSES AND OTHER LONG-TERM LIABILITIES

Accrued expenses consist of the following as of December 31, 2012 and 2011:

	2012	2011
Payroll costs	$ 892,564	$ 529,967
Taxes, primarily VAT	572,095	864,581
Professional fees	277,416	76,550
Royalties	82,562	67,184
Accrued acquisition costs	70,004	—
Accrued plant closing costs	274,888	—
Deferred revenue	406,840	—
Other	233,078	205,939
Balance as of December 31	$2,809,447	$1,744,221

10 ACCRUED EXPENSES AND OTHER LONG-TERM LIABILITIES – (continued)

Other long-term liabilities of $993,980 as of December 31, 2012, and $994,348 as of December 31, 2011, consist primarily of Italian employee leaving indemnity. Italian law provides that each employee is entitled to receive a payment upon severance of employment. The amounts vest immediately and are adjusted for inflation.

11 SHAREHOLDERS' EQUITY

Common Stock

On March 14, 2001, b2bstores.com Inc. (now known as ERBA Diagnostics, Inc.), IVAX Corporation 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.

On June 10, 2011, the Company amended its certificate of incorporation to increase the number of shares of authorized common stock from 50,000,000 to 100,000,000.

During the years ended December 31, 2012 and 2011, the Company entered into various agreements and transactions with its majority stockholder. See Note 14, *Related Party Transactions*.

Share Repurchase Program

In 2002, the Company's Board of Directors approved a program to repurchase up to 2,000,000 shares of the Company's publicly held common stock. During the years 2012 and 2011, 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.

11 SHAREHOLDERS' EQUITY – (continued)

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 options generally have a term of 10 years. The following charts summarize option activity (both outstanding and exercisable) as of December 31, 2012 and changes during the years ended December 31, 2012 and 2011 and under the Performance Plan and the 2009 Plan:

	Number of Shares	Weighted Average Exercise Price
Balance as of December 31, 2010	1,173,198	$2.09
Granted	92,788	$0.85
Expired	(170,116)	$6.50
Terminated	(75,000)	$0.50
Balance as of December 31, 2011	1,020,870	$1.36
Granted	100,000	$0.55
Balance as of December 31, 2012	1,120,870	$1.10

	Options Outstanding and Exercisable		
Range of Exercise Prices	Number of Shares	Weighted Average Remaining Contractual Life (In Years)	Weighted Average Price
$0.00 – $0.50	100,000	6.3	$0.48
$0.51 – $0.75	495,870	7.3	$0.59
$0.76 – $1.00	175,000	6.2	$0.96
$1.01 – $1.50	100,000	5.7	$1.20
$1.51 – $3.00	100,000	3.7	$1.56
$3.01 – $6.00	150,000	2.5	$4.37
	1,120,870	5.6	$1.10

The aggregate intrinsic value of options outstanding and exercisable as of December 31, 2012 was zero. As of December 31, 2012 and 2011, all outstanding options were vested and therefore there was no unrecognized compensation cost. No windfall tax benefits were recognized during the years ended December 31, 2012 or 2011.

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 domestic region includes the operations of Drew Scientific and its subsidiaries from and after the acquisition date of October 3, 2012; see Note 4, *Acquisition of Drew Scientific, Inc.* The European region contains Delta Biologicals, the Company's subsidiary located in Italy, and, from and after the acquisition date of October 3, 2012, Drew Scientific Limited Co. 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, 2012 and 2011:

	Domestic	European	Eliminations	Total
December 31, 2012:				
External net sales	$14,316,923	$ 5,032,081	$ —	$19,349,004
Intercompany sales	575,210	115,141	(690,351)	—
Net revenue	$14,892,133	$ 5,147,222	$ (690,351)	$19,349,004
(Loss) from operations	$ (821,019)	$ (382,142)	$ —	$(1,203,161)
Assets	$38,785,080	$ 6,163,472	$(20,394,784)	$24,553,768
Goodwill	$ 3,494,619	$ —	$ —	$ 3,494,619
December 31, 2011:				
External net sales	$11,507,270	$ 5,252,503	$ —	$16,759,773
Intercompany sales	530,219	265,937	(796,156)	—
Net revenue	$12,037,489	$ 5,518,440	$ (796,156)	$16,759,773
(Loss) from operations	$(1,371,651)	$(1,856,650)	$ —	$(3,228,301)
Assets	$10,536,408	$ 6,670,477	$ —	$17,206,885
Goodwill	$ 870,290	$ —	$ —	$ 870,290

13 COMMITMENTS AND CONTINGENCIES

Leases

As of December 31, 2012, the Company is a lessee under non-cancelable leases with third parties. These arrangements are described below.

ImmunoVision has a lease agreement, which commenced on August 1, 2000 and was amended in July 2012, for office and warehouse space in Bentonville, Arkansas. The amended lease expires on July 31, 2016 and provides for annual rent expense of $72,000 through July 31, 2014 and $73,440 through July 31, 2016.

Delta Biologicals has a lease agreement, which commenced on September 1, 2011, for office and warehouse space in Pomezia, Italy. The lease expires on August 31, 2017 and provides for annual rent expense of Euro 120,000 (equivalent to approximately $154,000 as of December 31, 2012). The lease also provides for one six-year renewal option.

JAS Diagnostics has a lease agreement, which commenced on January 1, 2010 and was amended in March 2013, for its corporate headquarters and warehouse facilities in Miami Lakes, Florida. The amended lease expires on December 31, 2019 and provides for annual rent expense for the existing space and two

13 COMMITMENTS AND CONTINGENCIES – (continued)

expansion premises, as follows for each of the succeeding five years: 2013, $198,800; 2014, $391,150; 2015, $405,440; 2016, $421,657; and 2017, $438,524. The amended lease also provides for one five-year renewal option at a market rental rate.

Drew Scientific has a lease agreement, which commenced on April 1, 2007, for office and warehouse space in Dallas, Texas. The lease expires on March 31, 2014 and provides for annual rent expense of $70,000.

Drew Scientific also has a lease agreement, which commenced on December 15, 2012, for office and warehouse space in Waterbury, Connecticut. The lease expires on December 14, 2013 and provides for an annual rent expense of $6,000. The lease also provides for two three-year renewal option at a market rental rate.

The Company has various equipment and vehicle operating leases with third parties that expire from March 2012 through February 2017.

Aggregate rent expense under all operating leases for the years ended December 31, 2012 and 2011 totaled approximately $496,000 and $326,000, respectively.

The future minimum lease payments for the next five years under these and other non-cancelable operating leases with initial or remaining terms of one year or more as of December 31, 2012 are as follows:

2013	$ 651,000
2014	579,000
2015	510,000
2016	474,000
2017	439,000
Total minimum lease payments	$2,653,000

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 (cost of $222,257, net of accumulated depreciation of $62,973). Depreciation of $25,205 in the year ended December 31, 2012 and $24,078 in the year ended December 31, 2011 was included in cost of sales. The lease expires in 2013. The balance of $21,947 as of December 31, 2012 is reflected in the accompanying consolidated balance sheet as a current capital lease obligation. Interest expense for the years ended December 31, 2012 and 2011 was $15,179 and $12,537, respectively.

Litigation, Claims and Assessments

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

14 RELATED PARTY TRANSACTIONS

Certain Relationships and Related Transactions

During the years ended December 31, 2012 and 2011, the Company sold products to Transasia and a subsidiary of ERBA Mannheim for a total amount of Euro 390,000 (equivalent to approximately $501,000) and Euro 348,000 (equivalent to approximately $487,000), respectively.

In the fourth quarter of 2011, Delta Biologicals entered into a contract research and development agreement with ERBA Mannheim, as amended, for a total of Euro 754,700, pursuant to which ERBA Mannheim has agreed to pay the subsidiary a total amount of Euro 133,000, equivalent to approximately $186,000, during the fourth quarter of 2011 and an additional Euro 621,700, equivalent to approximately $799,000, during the year ended December 31, 2012 for the results of certain research and development. For the years ended December 31, 2012 and 2011, contract research and development revenue under this agreement approximated Euro 650,000 (equivalent to approximately $836,000) and Euro 133,000 (equivalent to approximately $186,000), respectively.

The Company had net accounts receivable from ERBA Mannheim and Transasia of $644,000 and $387,000 as of December 31, 2012 and 2011, respectively, related to the above transactions. As of December 31, 2012, the Company had a receivable of $65,441 for the reimbursement of various expenditures on behalf of ERBA Mannheim; this amount is included in other current assets in the accompanying consolidated balance sheet.

On June 15, 2012, the Company entered into a use of name license agreement with ERBA Mannheim granting a royalty-free, non-exclusive license to use the name "ERBA" for an annual fee of one dollar. The license agreement will be terminated upon the earlier of (a) the transfer by ERBA Mannheim to the Company of all of ERBA Mannheim's rights, title and interest in and to the use of the name and any stylized logos or marks associated with the name (the date that such transfer becomes effective, the "Transfer Date") and (b) such time, if any, as ERBA Mannheim no longer owns, directly or indirectly, shares of the Company's common stock representing more than 50% of the issued and outstanding shares of such stock (the "Share Threshold Date"). Furthermore, ERBA Mannheim may terminate the license agreement at any time after June 15, 2013 and prior to the earlier of the Transfer Date and the Share Threshold Date: (a) upon providing the Company 180 days prior written notice of its intent to terminate and the date upon which the license agreement shall terminate; or (b) upon providing the Company 30 days prior written notice of any breach of the license agreement by the Company, which breach remains uncured at the end of such 30 day period.

In December 2012, JAS Diagnostics entered into a Research and Development Outsourcing Agreement with Erba Diagnostics France SARL ("Erba Diagnostics France"), pursuant to which JAS Diagnostics has agreed to pay Erba Diagnostics France a total amount of Euro 350,000 (equivalent to approximately $462,500), in seven monthly installments of Euro 50,000 from December 2012 through June 2013, for certain research and development endeavors. The initial payment of Euro 50,000 (equivalent to approximately $64,900) is included in research and development expenses in the accompanying consolidated statement of operations and comprehensive loss for the year ended December 31, 2012.

Common Stock and Equity Transactions

The Company entered into the Stock Purchase Agreement with ERBA Mannheim, on April 8, 2011, pursuant to which the Company agreed to sell and issue to ERBA Mannheim an aggregate of 20,000,000 shares of the Company's common stock for an aggregate purchase price of $15,000,000, or $0.75 per share of the Company's common stock, and warrants to purchase an additional 20,000,000 shares of the Company's common stock. The consummation of the investment contemplated by the Stock Purchase Agreement was subject to, among other things, the approval of holders of at least 66⅔% of the issued and outstanding shares of the Company's common stock (excluding any shares beneficially owned, directly or indirectly, by ERBA Mannheim). At the 2011 Annual Meeting of Stockholders held on June 10, 2011, the required approval of the Company's stockholders was achieved.

14 RELATED PARTY TRANSACTIONS – (continued)

On June 30, 2011, ERBA Mannheim paid the Company $5,000,000 in order to consummate the initial transactions contemplated by the Stock Purchase Agreement (the "Initial Closing"). As a result, at the Initial Closing, the Company issued to ERBA Mannheim 6,666,667 shares of common stock and, in connection with the consummation of the initial transactions contemplated by the Stock Purchase Agreement, a warrant to purchase an additional 20,000,000 shares of common stock (the "Warrant"). After giving effect to transaction costs of $399,700 relating to the Stock Purchase Agreement, the Company received net proceeds of $4,600,300 at the consummation of the initial transactions contemplated by the Stock Purchase Agreement. The Warrant has a five year term and an exercise price per share of the Company's common stock of $0.75 and is exercisable only to the extent that shares of the Company's common stock have been purchased under the Stock Purchase Agreement.

On April 16, 2012, ERBA Mannheim exercised, in part, the Warrant by paying an aggregate exercise price of $450,000 and, in connection therewith, the Company issued to ERBA Mannheim 600,000 shares of the Company's common stock. A total of 19,400,000 warrants remain unexercised as of December 31, 2012. As of December 31, 2012, the Warrant was exercisable for 14,733,334 shares of the Company's common stock.

Pursuant to amendments to the Stock Purchase Agreement on December 29, 2011 and October 3, 2012, each of which was unanimously approved by the independent directors on the Board of Directors, the Company and ERBA Mannheim agreed that the Company would sell and issue to ERBA Mannheim, and ERBA Mannheim would purchase from the Company, 8,666,667 shares of common stock at the second closing of the transactions contemplated by the Stock Purchase Agreement (the "Second Closing") for an aggregate purchase price of $6,500,000, or $0.75 per share, and 4,666,666 shares of common stock at the final closing of the transactions contemplated by the Stock Purchase Agreement (the "Final Closing") for an aggregate purchase price of $3,500,000, or $0.75 per share. In addition, pursuant to the amendments to the Stock Purchase Agreement, the Company and ERBA Mannheim agreed to hold the Second Closing as promptly as practicable on or after October 3, 2012 and to hold the Final Closing on the date that is 60 days after the date on which a majority of the independent directors on the Board of Directors determines by vote or written consent that such issuance, sale and purchase shall occur and causes notice thereof to be delivered to ERBA Mannheim.

The Second Closing was held on October 3, 2012, at which time ERBA Mannheim paid the $6,500,000 aggregate purchase price to the Company, and, in connection therewith, the Company issued to ERBA Mannheim 8,666,667 shares of the Company's common stock. As described in Note 4, *Acquisition of Drew Scientific, Inc.*, the Company used all of the proceeds of the Second Closing to consummate the acquisition of Drew Scientific.

Other Transactions

During the years ended December 30, 2012 and 2011, ImmunoVision has paid $24,000 annually to John B. Harley, M.D., Ph.D., a member of the Board of Directors, under that certain oral consulting agreement between Dr. Harley and ImmunoVision pursuant to which Dr. Harley is paid $2,000 per month in consideration for his provision of technical guidance and business assistance to the subsidiary on an as-needed basis.

Pursuant to a license agreement between the Company and Dr. Harley, he has granted an exclusive worldwide license to the Company for certain patents, rights and technology relating to monoclonal antibodies against autoimmune RNA proteins developed by him in exchange for specified royalty payments, including an annual minimum royalty of $10,000 for each licensed product utilized by the Company. For the year ended December 31, 2012, the Company has expensed the minimum $10,000 under such agreement.

The amounts paid to Dr. Harley were in addition to the amounts he received for his service as member of the Company's Board of Directors and the committees of the Board of Directors on which he served.

15 REVOLVING LINE OF CREDIT

On June 10, 2011, Diamedix entered into a Loan Agreement with City National Bank of Florida, which provided for a secured, revolving credit facility of up to $975,000 (the "Old Line of Credit"). As described in Note 16, *Subsequent Events*, the Company has closed down the Old Line of Credit and the Company entered into a new loan agreement with Citibank, N.A., which provides for a secured, revolving credit facility of up to $2,000,000. Amounts outstanding under the Old Line of Credit accrued interest at an annual rate equal to the 30-day LIBOR plus 4.00%, and the loan was to become due and payable on June 10, 2013, subject to acceleration upon the occurrence of certain specified events of default that the Company believes are customary for transactions of this type. The interest rate will increase by two percentage points (2%) per annum if certain covenants contained in the loan agreement are not met.

Amounts outstanding under the Old Line of Credit were collateralized by all of the assets of Diamedix, including, without limitation, the Company's corporate headquarters located in Miami, Florida. In addition, the Company and its other wholly-owned domestic subsidiary at the time, ImmunoVision, guaranteed the repayment of amounts drawn on the Old Line of Credit.

The loan agreement also included, among other things, the following financial covenants applicable to Diamedix:

- Minimum Tangible Net Worth (as defined therein) of not less than $1,000,000 as of December 31 of each year.
- Fixed Charge Coverage Ratio (as defined therein) of not less than 1.50 to 1.00 as of the last day of each fiscal quarter, as measured for compliance on a rolling four quarter basis.
- Maximum Funded Debt to EBITDA Ratio (as defined therein) of not less than 2.50 to 1.00 as of the last day of each fiscal quarter.

As of December 31, 2012 and 2011, the Company had not been notified and was not aware of any events of noncompliance with respect to the above financial covenants. Closing costs and other transaction costs aggregating $101,482 were incurred in 2011 related to the loan agreement and the Old Line of Credit. These costs have been classified as debt issuance costs on the accompanying consolidated balance sheets (included in other current assets) and are being amortized over the 24-month term of the Old Line of Credit commencing in June 2011. Amortization expense for the years ended December 31, 2012 and 2011 was $50,736 and $29,599, respectively; the unamortized balance as of December 30, 2012 was $29,599. The remaining balance will be written off in 2013 as a result of the refinancing on March 1, 2013, as further described in Note 16, *Subsequent Events.*

As of December 31, 2012 and 2011, $822,635 and $736,566, respectively, was outstanding under the Old Line of Credit. As of both dates, these amount and related debt issuance costs have been classified as current due to the terms of the related lockbox arrangement. As of December 31, 2012, the availability on the Old Line of Credit was $152,375.

16 SUBSEQUENT EVENTS

New Credit Facility

On March 1, 2013, the Company entered into that certain Business Loan Agreement and that certain Promissory Note with Citibank, N.A. ("Citibank"), which provides for a secured, revolving credit facility of up to $2,000,000 (the "New Line of Credit"). Amounts outstanding under the New Line of Credit will accrue interest at an annual rate equal to the 30-day LIBOR plus 1.75% and will become due and payable on December 31, 2013, subject to acceleration upon the occurrence of certain specified events of default that the Company believes are customary for transactions of this type. Pursuant to the business loan agreement, the Company will be subject to certain specified positive and negative covenants (including, without limitation, the requirements to maintain a specified capital base of not less than $8,500,000 and a specified leverage ratio, as defined, of not less than 2.0-to-1.0) that the Company believes are customary for transactions of this type.

16 SUBSEQUENT EVENTS – (continued)

Amounts outstanding under the New Line of Credit have been collateralized by all of the assets of the Company and its wholly-owned subsidiaries located in the United States — Diamedix, ImmunoVision, and Drew Scientific. In addition, each of Diamedix, ImmunoVision and Drew Scientific has guaranteed the repayment of amounts drawn on the New Line of Credit. Further, Transasia, the indirect parent company of the Company, has also guaranteed the repayment of amounts drawn on the New Line of Credit.

In connection with establishing the New Line of Credit, Diamedix contemporaneously closed down the Old Line of Credit with City National Bank of Florida, as described in Note 15, *Revolving Line of Credit.* The payoff amount at closing was $975,000.

The Company did not submit its annual and first quarter consolidated financial statements to Citibank as of the required dates. Citibank has issued a waiver for these two areas of noncompliance.

Cessation of Operations at Certain Drew Scientific Facilities

As more fully described in Note 4, *Acquisition of Drew Scientific, Inc.*, regarding the Dallas, Texas facility, in May 2013, the Company's management announced that the closing would be effective in late September 2013. With respect to the United Kingdom facility, the closing was effective in late March 2013.

Lease Commitment

As more fully described in Note 13, *Commitments and Contingencies*, JAS Diagnostics amended the lease agreement in March 2013 for its corporate headquarters and warehouse facilities in Miami Lakes, Florida.

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, because of the material weakness described below, our disclosure controls and procedures are not 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. Notwithstanding the material weakness described below, our management, including our principal executive officer and principal financial officer, has concluded that the consolidated financial statements included in this Annual Report on Form 10-K present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with GAAP.

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. As permitted by the applicable rules and regulations of the Securities and Exchange Commission, our management's evaluation of and conclusion on the effectiveness of our internal control over financial reporting did not include the internal control over financial reporting of the businesses commonly known as Drew Scientific and JAS Diagnostics, which we acquired on October 3, 2012 and which, collectively, at December 31, 2012 constituted assets of $9.0 million and represented 36.7% of our consolidated total assets and which, collectively, for the year ended December 31, 2012 generated $3.4 million of net revenues and represented 17.5% of our consolidated net revenues. Based upon that evaluation, our management concluded that our internal control over financial reporting was not effective as of December 31, 2012, because there was a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. Specifically, through that evaluation, our management identified a material weakness in our internal control over financial reporting as a result of our inadequate staffing of our financial accounting office, which has resulted in, among other things, at times us

being unable to provide timely account reconciliations. Our remediation efforts to address this material weakness are ongoing and include, among other things, hiring additional qualified personnel and evaluating or undertaking certain improvements to our systems and processes, which, if successful, we believe will be sufficient to provide us with the ability to remediate or cure this material weakness in the future. If this material weakness is not remediated or cured, then this deficiency in internal control over financial reporting could adversely affect the timing and accuracy of our financial reporting.

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 and regulations 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

Beginning in the fourth quarter of 2012, we began implementing accounting systems, as well as standards, policies and procedures, at the businesses commonly known as Drew Scientific and JAS Diagnostics, in an effort to ensure that we have in place appropriate internal control over financial reporting at the businesses commonly known as Drew Scientific and JAS Diagnostics. Additionally, we have begun our remediation efforts to address the material weakness as described above. Except as set forth in the preceding sentences with respect to the businesses commonly known as Drew Scientific and JAS Diagnostics and with respect to our efforts to remediate our material weakness in our internal control over financial reporting, there were no changes in our internal control over financial reporting that occurred during the quarter ended December 31, 2012 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 June 7, 2013.

Name	Age	Position
Suresh Vazirani	63	Executive Chairman of the Board of Directors
Kevin D. Clark	50	Chief Executive Officer, Chief Operating Officer and President
Mohan Gopalkrishnan	58	Vice President — Operations
Arlene Rodriguez	43	Controller
Kishore "Kris" Dudani	59	Director
Philippe Gadal, Pharm.D.	57	Director
Gerald E. Gallwas	76	Director
John B. Harley, M.D., Ph.D.	63	Director
Sanjiv Suri	54	Director
David M. Templeton	60	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 June 7, 2013. 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.

Suresh Vazirani has served as the Executive Chairman of the Board of Directors since September 2010. Mr. Vazirani has served as the Chief Executive Officer and Managing Director of ERBA Diagnostics Mannheim GmbH, 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 Mannheim, since 1985. As described above, ERBA Mannheim beneficially owns, directly or indirectly, approximately 82.4% 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. In addition, Mr. Vazirani serves as a Trustee of Moral Re-Armament, an organization located in Panchgani, India. Mr. Vazirani is the first cousin of Kishore "Kris" Dudani.

Kevin D. Clark was named our President and Chief Executive Officer in September 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.

Arlene Rodriguez has served as our Controller since February 9, 2012. Ms. Rodriguez previously served as the Director of Accounting for Continucare Corporation, a healthcare company, from 2010 through February 2012. Additionally, she was the Associate Finance Director of Stiefel Laboratories, a dermatology company, from 2007 through 2010. Ms. Rodriguez is a Certified Public Accountant with 18 years of experience working in global corporations in financial reporting and analysis positions.

Mohan Gopalkrishnan has served as our Vice President — Operations since October 22, 2012. Prior to joining our company, Mr. Gopalkrishnan spent the last 15 years with Becton Dickinson in a number of leadership roles including as Senior Director with global responsibility for the pre-analytical systems business unit, Business Director of the Asia-Pacific region, ERP Leader of the Asia-Pacific region and General Manager of the medical/surgical division.

Kishore "Kris" Dudani has served as a director on the Board of Directors since September 2010. Since 2004, Mr. Dudani has served as the Marketing and Business Development Representative — South, Central and Latin America, of ERBA Mannheim. 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 has served as a director on the Board of Directors since September 2010. Since January 2013, Dr. Gadal has served as the US Deputy for Industry Sales and Marketing for BioMerieux, an in vitro diagnostics company. 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 which specializes in hematology, from 1998 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.

Gerald Gallwas has served as a director on the Board of Directors since September 2011. Mr. Gallwas was a member of the original team that founded and managed the growth of what became the clinical diagnostic business of Beckman Instruments. He retired after 30 years of service. Mr. Gallwas currently serves on the boards of directors of Medica Corporation and the Arnold and Mabel Beckman Foundation and was previously the President of Sangy, Inc., an in vitro diagnostics consulting business. The Board of Directors believes that Mr. Gallwas' vast experience within the diagnostics industry provides him with the ability to contribute valuable insight to the Board of Directors with respect to our business and technologies and to offer valuable assistance in helping to guide us in the years ahead.

Dr. John B. Harley has served as a director on the Board of Directors since the Company's 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 was a member of the board of directors of JK Autoimmunity, Inc. and he currently is 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.

Sanjiv Suri has served as a director on the Board of Directors since May 8, 2013. Mr. Suri has served as President International Business of ERBA Mannheim since June 2011. Prior to that time, Mr. Suri had served in various roles with Bio-Rad Laboratories since 1985. The Board of Directors believes that Mr. Suri'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 international business with respect to in vitro diagnostic products will be valuable in helping to guide us in the years ahead.

David M. Templeton has served as a director on the Board of Directors since September 2010. Mr. Templeton has served as the President and Chief Operating Officer of Global Vet, a veterinary reference laboratory, since 2006 and the Chief Operating Officer of Catachem 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's appointment to the Board of Directors further strengthens its composition and 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.

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 MKT. 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, 2012.

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.erbadiagnostics.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.erbadiagnostics.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 MKT.

Audit Committee Members and Financial Expert

The members of the Audit Committee of our Board of Directors are: (i) Philippe Gadal, Pharm.D., Chairman and (ii) 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 MKT relating to directors serving on audit committees. Gerald E. Gallwas served as a member of the Audit Committee of our Board of Directors from September 26, 2011 to August 10, 2012, and Mr. Gallwas continues to serve as a member of our Board of Directors.

ITEM 11. EXECUTIVE COMPENSATION

Compensation of Named Executive Officers

Summary Compensation Table — 2012

The following table sets forth certain summary information concerning compensation which, during the fiscal years ended December 31, 2012 and 2011, 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, 2012, (ii) the only other individual serving as an executive officer at December 31, 2012, and (iii) one additional individual who, but for the fact that such individual was not serving as an executive officer at December 31, 2012, 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	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Kevin D. Clark,[1]	2012	$227,000	—	—	—	—	—	—	$227,000
Chief Executive Officer (Principal Executive Officer)	2011	$227,000	—	—	—	—	—	—	$227,000
Arlene Rodriguez,[2]	2012	$110,000	—	—	—	—	—	—	$110,000
Controller (Principal Financial Officer)	2011	—	—	—	—	—	—	—	—
Arthur R. Levine,[3]	2012	$ 71,923	—	—	—	—	—	$42,500[4]	$114,423
Former Chief Financial Officer	2011	$170,000	—	—	—	—	—	—	$170,000

(1) Mr. Clark was appointed as our Chief Executive Officer and President on September 3, 2010. Throughout the fiscal years ended December 31, 2012 and 2011, Mr. Clark served as, and Mr. Clark continues to serve as, our Chief Operating Officer and the Chief Operating Officer of ImmunoVision. Mr. Clark's employment agreement with us, as amended, expired in accordance with its terms on March 27, 2012. Mr. Clark's employment by us beyond March 27, 2012 is "at-will" and without any employment agreement and with an annual base salary of $227,000, and such employment may be terminated by Mr. Clark or us at any time.

(2) Ms. Rodriguez became our Principal Financial Officer on or about August 1, 2012 and joined our company as Controller on February 9, 2012. Prior to February, 2012, Ms. Rodriguez was not employed by us and, accordingly, she did not receive any compensation from us prior to February 9, 2012. Ms. Rodriguez's employment by us is "at-will" and without any employment agreement and with an annual base salary of $110,000, and such employment may be terminated by Ms. Rodriguez or us at any time.

(3) Mr. Levine served as our Chief Financial Officer, Vice President — Finance and Secretary until May 30, 2012, when his employment with us ceased. On April 5, 2010, Mr. Levine entered into an employment agreement with us, which was amended on September 1, 2010. In connection with the cessation of his employment with us, we and Mr. Levine entered into a confidential general release of all claims on June 21, 2012, pursuant to which, among other things, we agreed to pay Mr. Levine a one-time lump-sum payment of $42,500 in lieu of any compensation that he would otherwise have been entitled to receive in accordance with his employment agreement. The terms of Mr. Levine's employment agreement, as amended, which has now been terminated, and his confidential general release of all claims with us are described under "Potential Payments upon Termination or Change-in-Control" below.

(4) Represents a separation payment. Additional information about the separation payment to Mr. Levine is set forth under "Potential Payments upon Termination or Change-in-Control" below.

Outstanding Equity Awards at Fiscal Year-End — 2012

The following table sets forth certain information regarding equity based awards held by the Named Executive Officers as of December 31, 2012.

	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
Arthur R. Levine[1]	50,000	—	—	$0.65	4/4/20

(1) In accordance with its terms, the options to purchase 50,000 shares of our common stock granted to Mr. Levine have terminated. These options are included in this table because Mr. Levine is a Named Executive Officer.

Potential Payments upon Termination or Change-in-Control

Employment Agreement with Arthur R. Levine. Mr. Levine served as our Chief Financial Officer, Vice President — Finance and Secretary until May 30, 2012, when his employment with us ceased. 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 did not have a stated term. Under the employment agreement, Mr. Levine was paid an initial annual base salary of $135,000, and we agreed to review Mr. Levine's base salary at least annually. Mr. Levine's 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 MKT 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 was 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 2012 or 2011. In addition, under the employment agreement, we were 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 was 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 included 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 continued to serve as our Vice President — Finance.

Confidential General Release of All Claims with Arthur R. Levine. In connection with the cessation of Mr. Levine's employment with us on May 30, 2012, we and Mr. Levine entered into a confidential general release of all claims on June 21, 2012, pursuant to which, among other things, we agreed to pay Mr. Levine a one-time lump-sum payment of $42,500 in lieu of any compensation that he would otherwise have been entitled to receive in accordance with his employment agreement. We also agreed to reimburse Mr. Levine for COBRA premium payments made by him for COBRA coverage during the months of June, July and August 2012 for Mr. Levine and his spouse and dependents, subject to certain exceptions. Under the terms of the confidential general release of all claims, Mr. Levine provided a general release in favor of us. The confidential general release of all claims also contains an acknowledgement by Mr. Levine that he continues to be bound by non-disclosure, non-solicitation, anti-raiding and other restrictive 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 MKT rules relating to the independence of directors for their service on the Board, Audit Committee and Compensation Committee, on June 15, 2012, (i) each of our directors who was deemed to be "independent" under the NYSE MKT 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 MKT rules relating to the independence of directors was awarded a grant, effective as of two business days after the public announcement of the voting results of our annual meeting of stockholders, of options to purchase 25,000 shares of our common stock under our 2009 Equity Incentive Plan with an exercise price of $0.55 per share, which was the closing price of our common stock on the NYSE MKT on the effective date of grant, and which fully vested immediately upon the effective date of grant.

In accordance with our practice of compensating directors who are deemed to be "independent" under the NYSE MKT rules relating to the independence of directors for his services on the Board of Directors, Audit Committee and Compensation Committee, 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.

Upon their appointment on September 1, 2010, Suresh Vazirani and Kishore "Kris" Dudani stated that, as employees of ERBA Mannheim, they would not require any compensation for their service on the Board of Directors, Audit Committee or Compensation Committee. As a result, directors who were not deemed to be "independent" under the NYSE MKT rules relating to the independence of directors, including directors who are employed by us or ERBA Mannheim (including Suresh Vazirani, Kishore "Kris" Dudani and Sanjiv Suri), do not and will not receive any compensation for their service on the Board of Directors, Audit Committee or Compensation Committee.

Director Compensation — 2012

The following table sets forth certain information regarding the compensation paid to our directors for their service during the fiscal year ended December 31, 2012.

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards[1]	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Suresh Vazirani	—	—	—	—	—	—	—
Kishore "Kris" Dudani	—	—	—	—	—	—	—
Philippe Gadal, Pharm.D.	$32,500	—	$13,750	—	—	—	$46,250
Gerald E. Gallwas	$32,500	—	$13,750	—	—	—	$46,250
John B. Harley, M.D., Ph.D.	$20,000	—	$13,750	—	—	$24,000[2]	$57,750
Sanjiv Suri[3]	—	—	—	—	—	—	—
David M. Templeton	$32,500	—	$13,750	—	—	—	$46,250

(1) Represents the aggregate grant date fair value of option awards calculated in accordance with Codification Topic 718, *Compensation — Stock Compensation*. Assumptions used in the calculation of these amounts are included in Note 11 to our Consolidated Financial Statements, *Shareholders' Equity*. The table below sets forth, as of December 31, 2012, the aggregate number of stock options outstanding and exercisable by each of the individuals included in the table above:

Name	Stock Options
Suresh Vazirani	—
Kishore "Kris" Dudani	—
Philippe Gadal, Pharm.D.	64,041
Gerald E. Gallwas	42,788
John B. Harley, M.D., Ph.D.	190,000
Sanjiv Suri	—
David M. Templeton	64,041

(2) Represents the aggregate dollar amount earned by Dr. Harley during 2012 under that certain oral consulting agreement between Dr. Harley and ImmunoVision, pursuant to which Dr. Harley was paid $2,000 per month to provide ImmunoVision with technical guidance and business assistance on an as-needed basis.

(3) Mr. Suri joined the Board of Directors on May 8, 2013. Accordingly, during the year ended December 31, 2012, he was not a director and he did not receive any director compensation.

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 June 7, 2013, information about the beneficial ownership of our common stock by (i) each director, (ii) each Named Executive Officer, (iii) all directors and executive officers as of June 7, 2013 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	60,034,713	88.7%
Transasia Bio-medicals Ltd.[2] Transasia House 8 Chandivali Studio Road Mumbai, India 400072	60,034,713	88.7%
Suresh Vazirani[2] Transasia House 8 Chandivali Studio Road Mumbai, India 400072	60,034,713	88.7%
Kishore "Kris" Dudani[2] Transasia House 8 Chandivali Studio Road Mumbai, India 400072	60,034,713	88.7%
Kevin D. Clark	242,160[5]	*
Arthur R. Levine[3]	—	—
Philippe Gadal, Pharm.D.	64,041[6]	*
Gerald E. Gallwas	42,788[7]	*
John B. Harley, M.D., Ph.D.	190,000[8]	*
Sanjiv Suri[4]	—	—
David M. Templeton	64,041[9]	*
All directors and executive officers as of June 7, 2013 as a group (8 persons)	60,637,743	88.7%

* 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 60,026,313 shares of our common stock owned directly by ERBA Mannheim (of which 4,666,666 remain to be purchased by ERBA Mannheim under the Stock Purchase Agreement and 19,400,000 remain to be exercised by ERBA Mannheim under the Warrant, in each case, as further described throughout this Annual Report on Form 10-K) 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, and which Schedule 13D was amended by them on July 5, 2011. As set forth in the Schedule 13D, as amended, each of ERBA, Transasia and Messrs. Vazirani and Dudani may be deemed to have an aggregate beneficial ownership of 60,034,713, or 88.7%, 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) Mr. Levine served as our Chief Financial Officer, Vice President — Finance and Secretary until May 30, 2012, when his employment with us ceased. Mr. Levine is included in this table because he is a Named Executive Officer.

(4) Mr. Suri joined the Board of Directors on May 8, 2013.

(5) Includes options to purchase 100,000 shares of our common stock granted to Mr. Clark and 139,260 shares of our common stock owned by Mr. Clark through our 401(k) Plan.

(6) Includes options to purchase 64,041 shares of our common stock granted to Dr. Gadal.

(7) Includes options to purchase 42,788 shares of our common stock granted to Mr. Gallwas.

(8) Includes options to purchase 190,000 shares of our common stock granted to Dr. Harley.

(9) Includes options to purchase 64,041 shares of our common stock granted to Mr. Templeton.

Equity Compensation Plan Information

The following table sets forth information, as of December 31, 2012, 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	1,120,870	$1.10	3,405,318
Equity compensation plans not approved by stockholders	0	$ —	0
Total	1,120,870	$1.10	3,405,318

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

Controlling Stockholder

On September 1, 2010, ERBA Mannheim 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, the consummation of the various transactions contemplated by the investment made by ERBA Mannheim, as further described above, including ERBA Mannheim's purchase from us, and our issuance to ERBA Mannheim, of an aggregate of 15,333,334 shares of our common stock, and ERBA Mannheim's exercise, in part, of the Warrant, as further described above, for 600,000 shares of our common stock, ERBA Mannheim now beneficially owns, directly or indirectly, approximately 82.4% of the outstanding shares of our common stock.

Certain Relationships and Related Transactions

During the years ended December 31, 2012 and 2011, we sold products to Transasia and a subsidiary of ERBA Mannheim for a total amount of Euro 390,000 and Euro 348,000, respectively, equivalent to approximately $501,000 and $487,000, respectively.

In the fourth quarter of 2011, Delta Biologicals entered into a contract research and development agreement with ERBA Mannheim, as amended, for a total of Euro 754,000, pursuant to which ERBA Mannheim has agreed to pay the subsidiary a total amount of Euro 133,000, equivalent to approximately $186,000, during the fourth quarter of 2011 and an additional Euro 621,000 during the year ended December 31, 2012 for the results of certain research and development. For the years ended December 31, 2012 and 2011, contract research and development revenue under this agreement approximated Euro 650,000 (equivalent to approximately $836,000) and Euro 133,000 (equivalent to approximately $186,000), respectively.

We and our subsidiaries had net accounts receivable from ERBA Mannheim and Transasia of $644,000 and $387,000 as of December 31, 2012 and 2011, respectively, related to the above transactions.

In December 2012, JAS Diagnostics entered into a contract research and development agreement with ERBA Diagnostics France SARL, or ERBA Diagnostics France, pursuant to which JAS Diagnostics has agreed to pay ERBA Diagnostics France a total amount of Euro 350,000, equivalent to approximately $462,500, in seven monthly installments of Euro 50,000 from December 2012 through June 2013, for certain research and development endeavors.

We entered into the Stock Purchase Agreement with ERBA Mannheim, on April 8, 2011, pursuant to which we agreed to sell and issue to ERBA Mannheim an aggregate of 20,000,000 shares of our common stock for an aggregate purchase price of $15,000,000, or $0.75 per share of our common stock, and warrants to purchase an additional 20,000,000 shares of our common stock. The consummation of the investment contemplated by the Stock Purchase Agreement was subject to, among other things, 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 Mannheim). At our 2011 Annual Meeting of Stockholders held on June 10, 2011, the required approval of our stockholders was achieved.

On June 30, 2011, ERBA Mannheim paid us $5,000,000 in order to consummate the initial transactions contemplated by the Stock Purchase Agreement (the "Initial Closing"). As a result, at the Initial Closing, we issued to ERBA Mannheim 6,666,667 shares of our common stock and, in connection with the consummation of the initial transactions contemplated by the Stock Purchase Agreement, a warrant to purchase 20,000,000 shares of our common stock (the "Warrant"). After giving effect to transaction costs of $399,700 relating to the Stock Purchase Agreement, we received net proceeds of $4,600,300 at the consummation of the initial transactions contemplated by the Stock Purchase Agreement. The Warrant has a five year term and an exercise price per share of our common stock of $0.75 and is exercisable only to the extent that shares of our common stock have been purchased under the Stock Purchase Agreement.

On April 16, 2012, ERBA Mannheim exercised, in part, the Warrant by paying an aggregate exercise price of $450,000 to us and, in connection therewith, we issued to ERBA Mannheim 600,000 shares of our common stock. A total of 19,400,000 warrants remain unexercised as of December 31, 2012. As of December 31, 2012, the Warrant was exercisable for 14,733,334 shares of our common stock.

Pursuant to amendments to the Stock Purchase Agreement on December 29, 2011 and October 3, 2012, each of which was unanimously approved by the independent directors on the Board of Directors, we and ERBA Mannheim agreed that we would sell and issue to ERBA Mannheim, and ERBA Mannheim would purchase from us, 8,666,667 shares of our common stock at the second closing of the transactions contemplated by the Stock Purchase Agreement (the "Second Closing") for an aggregate purchase price of $6,500,000, or $0.75 per share, and 4,666,666 shares of our common stock at the final closing of the transactions contemplated by the Stock Purchase Agreement (the "Final Closing") for an aggregate purchase price of $3,500,000, or $0.75 per share. In addition, pursuant to the amendments to the Stock Purchase Agreement, we and ERBA Mannheim agreed to hold the Second Closing as promptly as practicable on or after October 3, 2012 and to hold the Final Closing on the date that is 60 days after the date on which a majority of the independent directors on the Board of Directors determines by vote or written consent that such issuance, sale and purchase shall occur and causes notice thereof to be delivered to ERBA Mannheim.

The Second Closing was held on October 3, 2012, at which time ERBA Mannheim paid the $6,500,000 aggregate purchase price to us and, in connection therewith, we issued to ERBA Mannheim 8,666,667 shares of our common stock. As described above, we used all of the proceeds of the Second Closing to consummate the acquisition of Drew Scientific.

On June 15, 2012, we entered into a use of name license agreement with ERBA Mannheim granting us a royalty-free, non-exclusive license to use the name "ERBA" for an annual fee of one dollar. The license agreement will be terminated upon the earlier of (a) the transfer by ERBA Mannheim to us of all of ERBA Mannheim's rights, title and interest in and to the use of the name and any stylized logos or marks associated with the name (the date that such transfer becomes effective, the "Transfer Date") and (b) such time, if any, as ERBA Mannheim no longer owns, directly or indirectly, shares of our common stock

representing more than 50% of the issued and outstanding shares of such stock (the "Share Threshold Date"). Furthermore, ERBA Mannheim may terminate the license agreement at any time after June 15, 2013 and prior to the earlier of the Transfer Date and the Share Threshold Date: (a) upon providing us 180 days prior written notice of its intent to terminate and the date upon which the license agreement shall terminate; or (b) upon providing us 30 days prior written notice of any breach of the license agreement by us, which breach remains uncured at the end of such 30 day period.

Director Independence

Our Board of Directors has determined that four of its members — Philippe Gadal, Pharm.D., John B. Harley, M.D., Ph.D., Gerald E. Gallwas and David M. Templeton — are "independent," as such term is defined in the applicable rules of the NYSE MKT relating to the independence of directors.

In determining that Mr. Gallwas is independent, our Board of Directors considered the consulting agreement between Mr. Gallwas' wife and ERBA Mannheim, pursuant to which Mr. Gallwas' wife is paid $6,000 monthly to provide ERBA Mannheim with technical guidance and business assistance on an as-needed basis.

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 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). Our Board of Directors also considered the license agreement between us and Dr. Harley pursuant to which Dr. Harley 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 2012, we accrued an aggregate payment of $10,000 to Dr. Harley under such license.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table sets forth the aggregate fees billed to us by Grant Thornton LLP, or GT, our principal accountant for the fiscal year ended December 31, 2011 and for the period ended May 15, 2012, and Mayer Hoffman McCann P.C., or MHM, which succeeded GT as our principal accountant effective on May 15, 2012 for the fiscal year ended December 31, 2012.

	For the years ended December 31,	
	2012	2011
Audit Fees	$190,000	$253,875
Audit-Related Fees	16,195	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	$206,195	$253,875

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-related fees" in the table above are attributed to professional services provided by MHM in connection with the pro forma financial statements and other financial information included in the current report on Form 8-K/A that we filed in connection with our acquisition of Drew Scientific.

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:

(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	Certificate of Amendment to the Amended and Restated Certificate of Incorporation	Incorporated by reference to Appendix B of our Schedule 14A filed on April 18, 2011.
3.3	Certificate of Amendment to the Amended and Restated Certificate of Incorporation	Incorporated by reference to Appendix A of our Schedule 14A filed on May 24, 2012.
3.4	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-Q filed on August 13, 2012.
4.2	Form of Warrant to Purchase Shares of Common Stock	Incorporated by reference to our Form 8-K filed on April 8, 2011.
10.1	Form of Indemnification Agreement between IVAX Diagnostics, Inc. (n/k/a ERBA 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, effective as of June 15, 2012, between ERBA Diagnostics, Inc. (f/k/a IVAX Diagnostics, Inc.) and ERBA Diagnostics Mannheim GmbH	Incorporated by reference to our Form 8-K filed on June 20, 2012.

Exhibit Number	Description	Method of Filing
10.3	Stock Purchase Agreement, dated April 8, 2011, by and between IVAX Diagnostics, Inc. (n/k/a ERBA Diagnostics, Inc.) and ERBA Diagnostics Mannheim GmbH	Incorporated by reference to our Form 8-K filed on April 8, 2011.
10.4	Amendment to Stock Purchase Agreement, dated December 29, 2011, by and between IVAX Diagnostics, Inc. (n/k/a ERBA Diagnostics, Inc.) and ERBA Diagnostics Mannheim GmbH	Incorporated by reference to our Form 8-K filed on December 29, 2011.
10.5	Second Amendment to Stock Purchase Agreement, dated October 3, 2012, by and between IVAX Diagnostics, Inc. (n/k/a ERBA Diagnostics, Inc.) and ERBA Diagnostics Mannheim GmbH	Incorporated by reference to our Form 8-K filed on October 5, 2012.
10.6	Stock Purchase Agreement, dated October 3, 2012, by and between Escalon Medical Corp., Drew Scientific, Inc., and ERBA Diagnostics, Inc.	Incorporated by reference to our Form 8-K filed on October 5, 2012.
10.7	Business Loan Agreement, dated as of March 1, 2013, by and between ERBA Diagnostics, Inc. and Citibank, N.A.	Incorporated by reference to our Form 8-K filed on March 7, 2013.
10.8	Form of Promissory Note, executed on March 1, 2013, made by ERBA Diagnostics, Inc. in favor of Citibank, N.A.	Incorporated by reference to our Form 8-K filed on March 7, 2013.
10.9	Form of Commercial Security Agreement, dated as of March 1, 2013, made by each of ERBA Diagnostics, Inc., Diamedix Corporation, ImmunoVision, Inc., and Drew Scientific, Inc., in favor of Citibank, N.A.	Incorporated by reference to our Form 8-K filed on March 7, 2013.
10.10	Form of Commercial Guaranty Agreement, dated as of March 1, 2013, made by each of Diamedix Corporation, ImmunoVision, Inc., and Drew Scientific, Inc., in favor of Citibank, N.A.	Incorporated by reference to our Form 8-K filed on March 7, 2013.
10.11	1999 Performance Equity Plan	Incorporated by reference to our Form SB-2 filed on October 6, 1999.
10.12	2009 Equity Incentive Plan	Incorporated by reference to our Schedule 14A filed on May 8, 2009.
10.13	Form of Nonqualified Stock Option Agreement (Employee)	Incorporated by reference to our Form 8-K filed on June 16, 2009.
10.14	Form of Nonqualified Stock Option Agreement (Independent Director)	Incorporated by reference to our Form 10-K filed on March 30, 2011.
21.1	Subsidiaries of ERBA Diagnostics, Inc.	Filed herewith.
23.1	Consent of Independent Registered Public Accounting Firm — Mayer Hoffman McCann, P.C.	Filed herewith.
23.2	Consent of Independent Registered Public Accounting Firm — Grant Thornton LLP	Filed herewith.
31.1	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith.

Exhibit Number	Description	Method of Filing
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	**
101.INS	XBRL Instance Document	***
101.SCH	XBRL Taxonomy Extension Schema Document	***
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	***
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document	***
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	***
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	***

* 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.

*** Pursuant to Rule 406T of SEC Regulation S-T, these interactive data files are deemed not filed or part of a registration statement or prospectus for purposes of Sections 11 or 12 of the Securities Act of 1933 or Section 18 of the Securities Exchange Act of 1934 and otherwise are not subject to liability under these sections.

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.

ERBA DIAGNOSTICS, INC.

Dated: June 14, 2013

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/ Suresh Vazirani Suresh Vazirani	Executive Chairman of the Board of Directors	June 14, 2013
/s/ Kevin D. Clark Kevin D. Clark	Chief Executive Officer, Chief Operating Officer and President (Principal Executive Officer)	June 14, 2013
/s/ Arlene Rodriguez Arlene Rodriguez	Controller (Principal Financial Officer) (Principal Accounting Officer)	June 14, 2013
/s/ Kishore Dudani Kishore Dudani	Director	June 14, 2013
/s/ Philippe Gadal, Pharm.D. Philippe Gadal, Pharm.D.	Director	June 14, 2013
/s/ Gerald E. Gallwas Gerald E. Gallwas	Director	June 14, 2013
/s/ John B. Harley, M.D., Ph.D. John B. Harley, M.D., Ph.D.	Director	June 14, 2013
/s/ Sanjiv Suri Sanjiv Suri	Director	June 14, 2013
/s/ David M. Templeton David M. Templeton	Director	June 14, 2013

We have made forward-looking statements in this annual report. Forward-looking statements may be preceded by, followed by or otherwise include the words "may," "will," "believes," "expects," "anticipates," "intends," "plans," "estimates," "projects," "could," "would," "should" or similar expressions or statements that certain events or conditions may occur. Actual results, performance or achievements could differ materially from those contemplated, expressed or implied by these forward-looking statements. These forward-looking statements are based largely on the expectations, beliefs and assumptions of our management and on the information currently available to it and are subject to a number of risks and uncertainties, including, but not limited to: the risks and uncertainties related to ERBA Diagnostics' financial condition, results of operations and cash flows, including, without limitation, that ERBA Diagnostics may not be able to improve its financial condition, revenue growth and cash flows, that ERBA Diagnostics may not be able to successfully maintain its cost containment efforts and reduced expenses, that ERBA Diagnostics may not be able to successfully consolidate its manufacturing and marketing operations when expected, if at all, and that even if ERBA Diagnostics is able to successfully consolidate its manufacturing or marketing operations, such consolidation may not enable ERBA Diagnostics to achieve significant operational or manufacturing efficiency or improvement in ERBA Diagnostics' competitiveness in the global marketplace, that ERBA Diagnostics may not be able to successfully achieve revenue growth and that ERBA Diagnostics' ongoing initiatives to reduce manufacturing costs, manage operating expenses, increase sales in the United States and other markets and otherwise improve its operating results may not be successful or result in the positive financial impact expected, whether in the time frame anticipated, or at all; the risks and uncertainties relating to the Hb-Vario and LISA XL, including, without limitation, that the Hb-Vario and LISA XL may not perform as expected, that the Hb-Vario or LISA XL may not result in revenue growth, increased market reach or improved operating results for ERBA Diagnostics and that ERBA Diagnostics' customers' may not integrate the Hb-Vario or LISA XL into their operations as readily as expected, in the time frame anticipated, or at all; the risks and uncertainties relating to diabetes products, including, without limitation, that ERBA Diagnostics' sales of diabetes products may not result in increased revenue or the positive financial impact expected and that the increase in the size of the global diabetes market may not expand where, or by as much, as expected; the risks and uncertainties surrounding the health care industry, including, without limitation, that the healthcare industry may not continue to grow; the risks and uncertainties related to ERBA Diagnostics' acquisition of Drew Scientific, Inc. and JAS Diagnostics, Inc., including, without limitation, that such acquisition may not increase ERBA Diagnostics' relevance to its customers, that such acquisition may not lead to or result in expanded product offerings by ERBA Diagnostics in areas including, without limitation, chemistry, hematology and diabetes testing globally, that such acquisition may not position ERBA Diagnostic to expand its market segments within the United States and globally, that such acquisition may not result in an expansion of its markets into the emerging markets (such as Asia, Africa and South America) and that the diabetes, hematology and chemistry range of products may not result in an increased revenue stream or otherwise have the positive financial impact expected, whether in the time frame anticipated, or at all; the risks and uncertainties relating to ERBA Diagnostics' technological, strategic and business initiatives, including, without limitation, that ERBA Diagnostics may not be able to expand its product offerings and market reach, including, without limitation, its ability to increase its sales and presence in key countries in Latin and South America as well as other international markets, that ERBA Diagnostics' new office in Mexico may not result in the positive financial impact expected, whether in the time frame anticipated, or at all, and that new products being registered with the regulatory bodies in Mexico and in other countries may not result in revenue growth and such new products may not gain registration when expected, or at all; the risk and uncertainty that ERBA Diagnostics' review of its policies, procedures and processes may not improve efficiency on an ongoing basis nor may it result in additional growth or business expansion when expected, if at all; the risks and uncertainties that ERBA Diagnostics will not experience significant consolidation or integration across all functions when expected, if at all, and that ERBA Diagnostics may not be able to successfully strengthen its management team or improve efficiencies; the risks and uncertainties that ERBA Diagnostics may not be able to successfully integrate and optimize its financial systems into one ERP platform when expected, or at all, and that even if ERBA Diagnostics is able to integrate its financial systems into one ERP platform, such integration may nevertheless not optimize all of the processes from sales and distribution management, supply chain, manufacturing and financial reporting, nor may it drive efficiencies across all functions and improve service to the customers and stakeholders of ERBA Diagnostics and that if ERBA Diagnostics is able to consolidate its manufacturing and marketing operations, it may not result in increased operational efficiency or improve its competitiveness in the global marketplace; the risks and uncertainties relating to ERBA Diagnostics' relationships with ERBA Diagnostics Mannheim GmbH, including, without limitation, that notwithstanding ERBA Diagnostics' change of name from IVAX Diagnostics to ERBA Diagnostics, ERBA Diagnostics may not be able to successfully develop brand recognition and collaboration through the worldwide network of ERBA companies, that ERBA Diagnostics Mannheim has voting control of ERBA Diagnostics' common stock and that conflicts of interest exist with ERBA Diagnostics Mannheim and with ERBA Diagnostics' officers, employees and other directors, including, without limitation, directors that are also executive officers of ERBA Diagnostics Mannheim; 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, 2012 which has been provided as a portion of this annual report. Many of these risks and factors are beyond our control.

14100 NW 57th Court
Miami Lakes, Florida 33014
(305) 324-2300

www.erbadiagnostics.com