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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, 2014

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 [X]

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 [X]

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 [X] 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 [X] 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. [X]

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 [X]
(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 [X]

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant on June 30, 2014, was approximately $15,593,000 computed by reference to the price at which the common equity was last sold on the NYSE MKT on such date.

As of May 8, 2015, there were 44,086,009 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, 2014

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PART I

ITEM 1. BUSINESS

General. We are the parent corporation of the following operating 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. 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, and Mago® Plus systems, include a fully-automated ELISA processor operating with our own user-friendly software, which allows customers to perform tests in an automated mode. We updated the Mago® Plus 4 and Mago® 4S instruments to include the capability to process ELISA and ImmunoFluorescent Assay, or IFA, simultaneously. 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 in Latin American and corporate operations. Our other segment - the European region - contains our subsidiary located in Italy. For additional information about our two segments, see Note 11, *Segment Information*, to our Consolidated Financial Statements.

Delta, our European segment, 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 costs. We believe that our proprietary Mago® 4, Mago® 4S and Mago® Plus 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. In Italy, Delta also sells other diagnostic products manufactured by third parties. During the year ended December 31, 2014 and 2013, approximately 63.2% and 69.4%, respectively, of Delta's revenue generated from customers in Italy was revenue from government owned hospitals and the remaining 36.8% and 30.6%, respectively, 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 of Italy.

Diamedix was established in 1986. 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 Lakes, Florida.

Drew Scientific was established in 1980. We acquired all of the issued and outstanding shares of capital stock of Drew Scientific from a subsidiary of Escalon Medical Corp., or Escalon, on October 3, 2012. 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). 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 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 (HbA1c). 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.

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. ImmunoVision is located in Springdale, Arkansas.

JAS Diagnostics was established in 2000. As described in further detail above, 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.

We were incorporated on June 28, 1999 under the laws of the State of Delaware. On June 15, 2012, our company's name was changed from "IVAX Diagnostics, Inc." to "ERBA Diagnostics, Inc."

Controlling Stockholder. 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 81.6% 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, 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 marked our entry into the important and strategic segment of diabetes management, which has so far been dominated by four companies. With the worldwide increased incidence of diabetes, we see that as a significant area of growth. Our focus has been to develop the next generation HbA1c for which we have recently received CE Mark and will shortly be applying for a 510(k) clearance for the US market.

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 $1,412,000 in 2014 and $1,920,000 in 2013 for research and development activities. Our research and development efforts have been targeted primarily towards the development of the next-generation instrument — LISA XL. In 2011, one of our subsidiaries entered into a contract research and development agreement with ERBA Mannheim pursuant to which ERBA Mannheim agreed to reimburse the subsidiary for the results of certain research and development. During 2014 and 2013, our subsidiary billed ERBA Mannheim for an additional Euro 436,000 (equivalent to approximately $579,000) and Euro 675,000 (equivalent to approximately $896,000), respectively, for research and development expenditures related to the above mentioned agreement.

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 market our products in the United States through our own sales force to hospitals, reference laboratories, clinical laboratories and research laboratories, as well as to other commercial companies that manufacture diagnostic products. We also distribute our products in the United States through certain independent distributors. We sell some of our products to pharmaceutical and biotechnology companies as well. 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 Lakes, 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 affected by the general reduction in business activity in Europe during the traditional summer vacation months.

While our business was not materially affected by working capital issues, our business was materially affected in the fourth quarter of 2014 by order backlog and the consolidation of our Diamedix and JAS manufacturing facilities.

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 May 8, 2015, we had 134 full time employees, of whom 15 were managerial, 62 were technical and manufacturing, 15 were administrative and 42 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 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 in the United States. 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.

If we are not able to remediate the material weakness relating to our internal control 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.

Until April 30, 2015, we did not have a Chief Financial Officer and our Controller had been our Principal Financial Officer and Principal Accounting Officer. Our Controller resigned effective as of April 30, 2015. Effective May 1, 2015, we hired and appointed a Chief Financial Officer. Our Chief Financial Officer will report to our Chief Executive Officer. Because our Chief Financial Officer joined the company during the second fiscal quarter of 2015, our Chief Executive Officer will serve as our Principal Financial Officer and Principal Accounting Officer until such time as we have filed this Annual Report on Form 10-K and our Quarterly Report on Form 10-Q for the first fiscal quarter of 2015 with the Securities and Exchange Commission. At such time that we have made both filings, our Chief Financial Officer will then assume the responsibilities of our Principal Financial Officer and Principal Accounting Officer.

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 or could affect the timing of our financial reporting, all of which could have an adverse effect on our business, financial condition or results of operations.

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

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, 2014, 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, 2014, 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, 2014, 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, 2014, 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 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. Additionally, 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. 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 were to occur, then we may not have adequate cash resources to fund our operations or liquidity needs for the reasonably foreseeable future.

While we have entered into a purchase and sale agreement to sell our former facilities located in Miami, Florida, the sale of our former facilities may not be consummated on the contemplated terms, in the time frame anticipated, or at all.

On March 25, 2015, our wholly-owned subsidiary located in Miami Lakes, Florida – Diamedix – entered into a Purchase and Sale Agreement with Joe Management LLC, as buyer, for the sale of the real property owned by Diamedix located at 2115, 2140, 2141, 2150, 2155, 2160 North Miami Avenue and 38 NW 22nd Street, in Miami, Florida, and all improvements thereon, or collectively, the Property. The purchase price for the Property is $23,000,000. As of December 31, 2014, the net book value of the land, buildings and improvements being sold was approximately $0.4 million.

The Purchase and Sale Agreement provides for a 45-day examination period, during which the buyer has the right to conduct a due diligence investigation of the Property and terminate the Purchase and Sale Agreement in its sole and absolute discretion. While the Purchase and Sale Agreement is binding upon Diamedix, the buyer, in its sole and absolute discretion, may terminate the Purchase and Sale Agreement during the 45-day examination period, in which case our sale of the Property would not be consummated. On May 8, 2015, the buyer and Diamedix amended the Purchase and Sale Agreement to extend the examination period to June 19, 2015.

The Purchase and Sale Agreement provides for the consummation of the purchase and sale of the Property to occur within 60 days after the expiration of the extended examination period. The Purchase and Sale Agreement may be assigned by the buyer without the consent of Diamedix.

Either Diamedix or the buyer may consummate the sale and purchase, respectively, of the Property as part of a like kind exchange pursuant to Section 1031 of the Internal Revenue Code, or a 1031 Exchange. If Diamedix elects a 1031 Exchange and intends to purchase a replacement property with a portion of the purchase price, then a qualified independent third party intermediary will be required to hold such portion of the purchase price that is designated to be used by Diamedix to purchase the replacement property in such 1031 Exchange, and, in which case, Diamedix will not have access to such portion of the purchase price. After the consummation of the purchase and sale of the Property under the Purchase and Sale Agreement, Diamedix would have 45 days to identify the replacement property for the 1031 Exchange. The purchase of the replacement property in the 1031 Exchange would need to be consummated by the earlier to occur of 180 days after the consummation of the purchase and sale of the Property under the Purchase and Sale Agreement and the due date, including extensions, of Diamedix's tax return for the tax year in which the consummation of the purchase and sale of the Property under the Purchase and Sale Agreement occurs.

Upon entering into the Purchase and Sale Agreement, the buyer placed into escrow an initial deposit of $100,000. If the buyer terminates the Purchase and Sale Agreement during the extended examination period, then the initial deposit will be returned to the buyer. If the buyer does not terminate the Purchase and Sale Agreement during the extended examination period, then, upon the expiration of such examination period, the buyer will be required to place into escrow an additional deposit of $400,000. After the expiration of the extended examination period, in the event of a default under the Purchase and Sale Agreement by the buyer, Diamedix would be entitled to receive the initial deposit and the additional deposit as its sole remedy. After the expiration of the extended examination period, in the event of a default under the Purchase and Sale Agreement by Diamedix, the buyer would be entitled to terminate the Purchase and Sale Agreement and receive the initial deposit and the additional deposit or attempt to specifically enforce the performance by Diamedix of its obligations under the Purchase and Sale Agreement.

Acquisitions and our efforts to continue integrating these acquired businesses may disrupt our business operations and distract our management and may not proceed as planned.

Acquisitions and our efforts to continue integrating 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. These 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; and
- exposure to unforeseen liabilities of the acquired businesses.

As a result of these or other problems and risks, businesses we acquire 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 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. To that effort, during 2015, we have hired a Chief Financial Officer, a Senior Vice President of Sales and a Vice President of Operations, all experienced with larger global businesses.

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, 2014, we recorded net revenues of $26.4 million and net income of $0.4 million. For the year ended December 31, 2013, we recorded net revenues of $28.3 million and net income of $0.7 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 2012 and 2011, we enacted various measures to reduce expenses in order to improve future cash flow. As a result, our operating results improved in 2013 and 2014 from the operating results achieved during 2011 and 2012. During 2011, we entered into the stock purchase agreement with ERBA Mannheim. On March 1, 2013, we entered into a $2,000,000 line of credit with Citibank, N.A., which we replaced with a new line of credit of up to $3,500,000 on March 24, 2015. 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.

We have become non-compliant with the continued listing standards of the NYSE MKT. 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, then our common stock could be delisted from the NYSE MKT.

On April 17, 2015, we received a letter from NYSE MKT LLC (the "Exchange") stating that the Exchange has determined that we are not in compliance with Sections 134 and 1101 of the Exchange's Company Guide (the "Company Guide") due to our failure to timely file our Annual Report on Form 10-K for the year ended December 31, 2014 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, 2014 is a material violation of its listing agreement with the Exchange and, therefore, pursuant to Section 1003(d) of the Company Guide, the Exchange is authorized to suspend and, unless prompt corrective action is taken, remove the Company's securities from the Exchange.

On May 1, 2015, we submitted a plan of compliance (the "Plan") addressing how we intend to regain compliance with Sections 134 and 1101 of the Company Guide by July 16, 2015 (the "Plan Period"). If our Plan is accepted by the Exchange, then we may be able to continue our listing during the Plan Period, during which time we will be subject to periodic review to determine whether we are making progress consistent with the Plan. If our Plan is not accepted by the Exchange, then we will be subject to delisting proceedings. Furthermore, if the Plan is accepted by the Exchange, but we are not in compliance with the continued listing standards of the Company Guide by July 16, 2015, or if we do not make progress consistent with the Plan during the Plan Period, then the Exchange staff will initiate delisting proceedings as appropriate.

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, 2014 and December 31, 2013, $2.1 million and $4.6 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, 12% at December 31, 2014 and 24% at December 31, 2013 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, 2014 and 2013, our accounts receivable were $7.4 million and $6.6 million, respectively, and our allowance for doubtful accounts was $0.9 million and $1.1 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 development and future commercial release of new products such as the next generation ELISA platform–the LISA XL, and the Hb Vario instrument system, may not be successful.

The development and marketing of new or enhanced products, including, without limitation, the LISA XL and Hb Vario instrument systems, is a complex and uncertain process. Accordingly, we cannot be certain that:

- the LISA XL or the Hb Vario instrument systems will perform as expected,
- the LISA XL or the Hb Vario instrument systems will enable us to expand the menu of test kits we offer,
- the LISA XL or the Hb Vario instrument systems will be a source of revenue growth for us,
- we will receive financial benefits or achieve improved operating results as a result of the future commercial release of the LISA XL or the Hb Vario instrument systems,
- we will be successful in the marketing of the LISA XL or the Hb Vario instrument systems, or
- customers will integrate the LISA XL or the Hb Vario instrument systems into their operations as readily as expected.

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

Our future success depends on portfolio expansion, global geographic expansion, market segmentation and market focus strategies, and the development of new markets.

Our success depends, in large part, on expanding our portfolio of products and on our ability to broaden sales of our existing products both in the United States and globally. Through our legacy operations, we have historically developed, manufactured and marketed diagnostic test kits, or assays, and automated instrument systems that are used to aid in the detection of disease primarily in the areas of autoimmune, infectious diseases and clinical chemistry. Our 2012 acquisition of Drew Scientific now allows us to design, manufacture and distribute instrument systems for blood cell counting and blood analysis, to sell diabetic testing products including the DS5 instrument, dispenser and associated reagent kit, which measure long-term glucose control in diabetic patients (HbA1c), and to offer a broad array of equipment for use in the field of human and veterinary hematology. Additionally, our 2012 acquisition of JAS Diagnostics now allows us to manufacture a broad range of liquid stable, diagnostics chemistry reagents used for in vitro diagnostics testing as well as to sell many general chemistry reagents that can be used on numerous open system chemistry instrument analyzers. In an effort to penetrate the market more effectively, we intend to continue expanding our portfolio of products in the areas of autoimmune, infectious diseases, clinical chemistry, hematology and diabetes testing, as well as continue increasing our sales and marketing activities in the United States and throughout the world.

Our success also largely depends 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 an effort to penetrate the market more effectively, we intend 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 any of the activities or programs described above or any other activities or programs will be successful. The failure of any 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 Lakes, 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 2014, we incurred approximately $1.4 million on our research and development efforts. We may in the future increase the amounts we spend on research and development depending upon, among other things:

- the outcome of clinical testing of products under development,
- delays or changes in government required testing or approval procedures,
- technological and competitive developments,
- strategic marketing decisions, and
- liquidity.

As a result, our research and development expenditures may adversely impact our earnings and cash flows in the short term. Additionally, there is no assurance that:

- our research and development expenditures will result in the development of new products or product enhancements,
- we will successfully complete products currently under development,
- we will obtain regulatory approval for any such products, or
- any approved product will be produced in commercial quantities, at reasonable costs, and be successfully marketed.

The markets for our products are highly competitive and subject to rapid technological change.

The markets for our products are highly competitive and are characterized by continual and rapid technological developments that have resulted, and will likely continue to result, in substantial improvements in product function and performance. Our success will depend, in part, on our ability to anticipate changes in technology and industry requirements and to respond to technological developments on a timely basis, either internally or through strategic alliances. Several companies have developed, or are developing, scientific instruments and assays that compete, or will compete, directly with products marketed by us. Many existing and potential competitors have substantially greater financial, marketing, research and technological resources, as well as established reputations for success in developing, manufacturing, selling and servicing products, than us. Competitors that are more vertically integrated than us may have more flexibility to compete effectively on price. We expect that existing and new competitors will continue to introduce products or services that are, directly or indirectly, competitive with those sold by us. Such competitors may succeed in developing products that are more functional or less costly than those sold by us and may be more successful in marketing such products. These and other changes and innovations in the rapidly changing medical technology market may negatively affect the sales of the products we market. There can be no assurance that we will be able to compete successfully in this market or that technology developments by our competitors will not render our current or future products or technologies obsolete. If we fail to effectively compete or adapt to changing technology, it could have a material adverse effect on our business, prospects, operating results or financial condition.

Our success depends on key personnel, the loss of whom could disrupt our business.

Our business is dependent on the active participation of our principal executive officers. The loss of the services of any of these individuals could adversely affect our business and future prospects. In addition, our success is dependent on our ability to retain and attract additional qualified management, scientists, engineers, developers and regulatory and other personnel. Competition for such talent is intense and there can be no assurance that we will be able to attract and retain such personnel. During 2015, we hired a Chief Financial Officer, a Senior Vice President of Sales and a Vice President of Operations, all experienced with larger global businesses.

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.

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 was 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. Additionally, in October 2012, with the acquisition of Drew Scientific, we recorded goodwill of $2.6 million. No impairment charge was recorded for the goodwill at ImmunoVision or Drew Scientific for 2014 or 2013. However, a decline in our market capitalization or sales by ImmunoVision or Drew Scientific could require us to record impairment charges in future periods for the goodwill recorded for ImmunoVision or Drew Scientific, as the case may be, 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 what additional healthcare reform proposals will be adopted or what impact the recently approved federal legislation may have on our business and operations. Any impact of the recently approved federal legislation, or additional healthcare reform proposals, 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 Lakes, 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, 2014 and 2013, Delta represented 21% and 18%, 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, 2014 and 2013, 21% and 18%, 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.

On March 25, 2015, we entered into a new line of credit with Citibank, N.A., which provides for a secured, revolving credit facility of up to $3,500,000. This new line of credit has replaced our old line of credit with Citibank, which provided for a secured, revolving credit facility of up to $2,000,000. The old line of credit is no longer outstanding. As of December 31, 2014, we had approximately $1,940,000 of indebtedness outstanding under the old line of credit with Citibank. 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 revolving line of credit with Citibank are collateralized by all of our assets and all of the assets of our wholly-owned subsidiaries located in the United States – Diamedix, ImmunoVision, Drew Scientific and JAS. Amounts outstanding under the revolving line of credit are also secured by our pledge of up to 66% of the total combined voting power of all classes of capital stock and other equity interest entitled to vote of our wholly-owned subsidiary located in Italy – Delta. In addition, each of Diamedix, ImmunoVision, Drew Scientific and JAS has guaranteed the repayment of amounts outstanding under the revolving line of credit. Further, Transasia, our indirect parent company, has also guaranteed the repayment of amounts outstanding under the revolving line of credit.

The loan agreement, pursuant to which the revolving line of credit with Citibank 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 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 81.6% 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 88.1% 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 Kishore "Kris" Dudani, who served as the Marketing and Business Development Representative—South, Central and Latin America of ERBA Mannheim until his retirement in May 2014, currently serves as a member of our board of directors. Transasia Bio-Medicals Ltd. is the parent company of ERBA Mannheim.

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 in June 2012, 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 has the right to terminate the license agreement at any time 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 81.6% 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 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;
- the sale by Diamedix of our former facilities located in Miami, Florida, may not be consummated on the contemplated terms, in the time frame anticipated, or at all;
- under the purchase and sale agreement to sell our former facilities located in Miami, Florida, the buyer, in its sole and absolute discretion, may terminate the purchase and sale agreement during the extended examination period which runs until June 19, 2015;
- if Diamedix elects to undertake a 1031 Exchange and purchase a replacement property with a portion of the purchase price, then Diamedix will not have access to such portion of the purchase price and Diamedix may not be able to consummate any such further transaction when anticipated, or at all;
- Diamedix may not elect to undertake a 1031 Exchange or purchase a replacement property;
- our ability to pay when due the principal and interest on our outstanding indebtedness under the revolving 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 revolving line of credit;
- our ability to remediate our material weakness relating to our internal control 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;
- our ability to successfully market the DSX™ and DS2™ instrument systems from Dynex Technologies in conjunction with our test kits on a worldwide basis;
- our ability to successfully market the Mago 4S instrument system, Ds5 instrument system for diabetes testing, the Ds360 instrument system for diabetes testing, the D3 instrument system for hematology testing, and the 2280 instrument system for hematology testing;
- our ability to successfully market generic clinical chemistry reagents;
- our ability to expand the menu of test kits that we offer to include other complementary infectious disease or autoimmune testing sectors or otherwise;
- our ability to expand our portfolio of products;
- our ability to expand geographically;
- our ability to successfully execute market segmentation and market focus strategies;
- 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 continue integrating 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 continue integrating Drew Scientific and JAS Diagnostics;
- our ability to achieve economies of scale or to maximize the utilization of our assets and facilities, after continued integration of 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;
- 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;
- 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 goodwill recorded at ImmunoVision and Drew Scientific, 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 derive revenue growth from our manufacture and sale of our own hepatitis products;
- 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 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 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.

Drew Scientific leases approximately 1,100 square feet of commercial space in Waterbury, Connecticut and approximately 12,000 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. JAS Diagnostics leases approximately 30,000 square feet of commercial space in Miami Lakes, Florida, where it manufactures reagents for hematology and clinical chemistry. In January 2014, we began leasing an additional 30,000 square feet of space in Miami Lakes, Florida in an effort to consolidate our Florida operations, which was completed in November 2014, and our Texas manufacturing operations, which we plan to consolidate in 2015.

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.

Diamedix owns approximately 52,000 square feet of buildings at its facility in Miami, Florida. From this facility, Diamedix conducted research and development of in vitro diagnostic products and reagent kit manufacturing. In October 2014, we moved the Diamedix manufacturing operations into our Miami Lakes, Florida, facility.

On March 25, 2015, our wholly-owned subsidiary located in Miami Lakes, Florida – Diamedix – entered into a Purchase and Sale Agreement with Joe Management LLC, as buyer, for the sale of the real property owned by Diamedix located at 2115, 2140, 2141, 2150, 2155, 2160 North Miami Avenue and 38 NW 22nd Street, in Miami, Florida, and all improvements thereon, or collectively, the Property. The purchase price for the Property is $23,000,000. The Purchase and Sale Agreement provides for a 45-day examination period, during which the buyer has the right to conduct a due diligence investigation of the Property and terminate the Purchase and Sale Agreement in its sole and absolute discretion. While the Purchase and Sale Agreement is binding upon Diamedix, the buyer, in its sole and absolute discretion, may terminate the Purchase and Sale Agreement during the 45-day examination period, in which case our sale of the Property would not be consummated. On May 8, 2015, the buyer and Diamedix amended the Purchase and Sale Agreement to extend the examination period to June 19, 2015. The Purchase and Sale Agreement provides for the consummation of the purchase and sale of the Property to occur within 60 days after the expiration of the extended examination period.

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 and trades under the symbol "ERB."

As of the close of business on May 8, 2015, 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 2014 and 2013, as reported by the NYSE MKT:

2014	High	Low
Fourth Quarter	$ 3.60	$ 2.48
Third Quarter	4.13	1.65
Second Quarter	2.68	1.39
First Quarter	4.13	2.02

2013	High	Low
Fourth Quarter	$ 3.10	$ 1.29
Third Quarter	1.65	0.70
Second Quarter	0.95	0.62
First Quarter	0.93	0.69

We did not declare or pay cash dividends on our common stock during 2014 or 2013, 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 the information contained in our Consolidated Financial Statements and the related Notes to the Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

OVERVIEW

We are the parent corporation of the following operating 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, urinalysis, 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, Drew Scientific, ImmunoVision, JAS Diagnostics and Erba Diagnostics Mexico S.A., our subsidiaries located in the United States and Latin America, and corporate operations. Our other segment—the European region—contains Delta Biologicals, our subsidiary located in Italy, and, from October 2012 until March 2013, Drew Scientific Limited Co., our subsidiary which was located in the United Kingdom. For financial information related to these segments, see Note 11, *Segment Information*, to the Consolidated Financial Statements.

Majority Stockholder

ERBA Mannheim, an in vitro diagnostics company headquartered in Germany, the parent company of which is Transasia Bio-Medicals Ltd., or Transasia, is the beneficial owner, directly or indirectly, of approximately 81.6% of the outstanding shares of our common stock.

CRITICAL ACCOUNTING POLICIES

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America, or 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

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 composed of gross revenue less provisions for expected product returns, allowances, discounts and warranty claims.

We also own instruments that we place, under "reagent rental" programs common to the industry, for periods of time at customer facilities for usage with our products ("Equipment on Lease"). The instrument system, which remains our property (or, in the case of a lease financing arrangement, that of the financing 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 us.

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.

Cost of Sales and Gross Margins

We strive to control our costs of revenue and thereby maintain our gross margins. Significant items impacting cost of sales include component prices and our direct technical and production personnel costs. Our gross margins have remained relatively stable; however, factors such as sales price, product mix, inventory obsolescence, returns, component price increases and increases in our direct production personnel costs, significantly impact our gross margins from quarter to quarter and represent indicators we monitor on a regular basis.

Operating Expenses

Operating expenses are substantially driven by personnel and related overhead expenses. Significant operating expenses that we monitor include selling, administrative, and research and development.

Liquidity and Cash Flows

Our financial condition remains strong with significant cash, overall significant working capital, and limited long-term liabilities for severance in Italy and deferred income taxes. The change in our cash position was primarily due to cash used in operating activities and cash used for capital expenditures.

Balance Sheet

We view cash, accounts receivable, inventory, accounts payable, and our revolving line of credit as important indicators of our financial health. Utilization of our revolving line of credit has increased due to increased capital expenditures for our plant relocation and the length of time that it takes to collect on accounts receivable.

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 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 includes components for current or future versions of products and instrumentation.

Goodwill, Other Intangibles, and Fixed Assets

Goodwill represents the excess purchase price over the estimated fair value of net assets acquired as of the acquisition date. We test goodwill for impairment on an annual basis and between annual tests when impairment indicators are identified, and goodwill is written down when impaired. Goodwill was recognized in connection with the acquisition of ImmunoVision and the more recent acquisition of Drew Scientific. We perform our annual goodwill impairment test during the last quarter of the fiscal year. No impairment charge was recorded for the goodwill at ImmunoVision or Drew Scientific during 2014 or 2013.

As part of our annual goodwill impairment test, we first perform a qualitative assessment to determine whether further impairment testing is necessary. If, as a result of the qualitative assessment, it is more-likely-than-not (i.e. greater than 50% chance) that the fair value of the reporting unit is less than the carrying amount, then the quantitative impairment test will be required. Otherwise, no further testing will be required.

Examples of events and circumstances that might indicate that a reporting unit's fair value is less than its carrying amount include macro-economic conditions such as deterioration in the entity's operating environment or industry or market considerations; entity-specific events such as increasing costs, declining financial performance, or loss of key personnel; or other events such as an expectation that a reporting unit will be sold or a sustained decrease in its stock price on either an absolute basis or relative to peers.

If it is determined, as a result of the qualitative assessment, that it is more-likely-than-not that the fair value of the reporting unit is less than the carrying amount, then the provisions of authoritative guidance require that we perform a two-step impairment test on goodwill. The first step of the test identifies whether potential impairment may have occurred, while the second step of the test measures the amount of impairment, if any. Impairment is recognized when the carrying amount of goodwill exceeds its fair value.

We review for impairment our long-live assets, including other intangibles and fixed assets that are held and used in our 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 we 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 future undiscounted cash flows is less than the carrying amount of the related assets, then we will recognize an impairment loss.

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 using the straight-line attribution method over the requisite service period of the related award, which is generally the option vesting term of (i) immediately or (ii) in equal annual amounts over a four-year period. We recorded total compensation expense of $73,000 and $134,000 for the years ended December 31, 2014 and 2013, respectively.

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 has been 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 periods of time that the 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 are required to estimate our income taxes in each of the jurisdictions in which we operate as part of the process of preparing our consolidated financial statements. This process involves estimating our actual current tax exposure, including assessing the risks associated with tax audits, together with assessing temporary differences resulting from the different treatment of items for tax and accounting purposes.

Prior to 2013, 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 (i.e. greater than 50% chance) 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, 2014. 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 carry forwards 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 carry forwards 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 our common stock. As a result of that acquisition, our ability to utilize net operating loss carry forwards 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, 2014 and 2013 were not impacted by these limitations.

RESULTS OF OPERATIONS

YEAR ENDED DECEMBER 31, 2014 COMPARED TO YEAR ENDED DECEMBER 31, 2013

Net income for the year ended December 31, 2014 was $450,000, compared to net income of $676,000 for the year ended December 31, 2013. The $226,000, or 34%, decrease was attributed to the following:

Net revenues decreased by $1,863,000 to $26,392,000 in 2014 from $28,255,000 in 2013. This 7% decrease was primarily attributed to a decrease in net revenues of $2,231,000 from domestic operations during 2014, compared to 2013, due to a number of factors including the move of the facility location which caused disruption in production/operation and changes in the sales organization as well as reduced headcount from attrition and reorganization initiatives. Such decrease was partially offset by an increase in net revenues from European operations.

Cost of sales decreased $664,000 to $13,778,000 in 2014 from $14,442,000 in 2013. This 5% decrease was primarily related to the changes in net revenues as mentioned above.

Gross profit decreased by $1,199,000 to $12,614,000 in 2014 from $13,813,000 in 2013. This 9% decrease was primarily related to the reduction in net revenues from domestic operations as mentioned above. Gross profit margins dropped to 47.8% in 2014 from 48.9% in 2013 as a result of the lower volume as well as manufacturing inefficiencies and higher costs due to the facility move.

Total operating expenses decreased by $1,035,000 to $11,741,000 in 2014 from $12,776,000 in 2013. The 8% decrease was primarily a result of decreases in selling expenses and research and development expenses, partially offset by an increase in general and administrative expenses. Selling expenses decreased $1,270,000, or 24%, to $4,039,000 in 2014 from $5,309,000, in 2013, which is primarily attributable to the reorganization of the salesforce. General and administrative expenses increased $743,000, or 14%, to $6,290,000 in 2014 from $5,547,000 in 2013 due to moving expenses, additional rent for Drew Scientific's expanded facility, higher depreciation from increased fixed assets related to the move and the implementation of a new ERP system. Research and development expenses decreased by $508,000, or 26%, to $1,412,000 in 2014 from $1,920,000 in 2013 as a result of lower spending in our European operations as we reached the prototype stage of development for the next generation ELISA platform – LISA XL and lower spending in the domestic operations as we downsized headcount.

Operating income was $873,000 in 2014 compared to an operating income of $1,037,000 in 2013, a decrease of $164,000, or 16%. The decrease in operating income in 2014 as compared to 2013 resulted primarily from the reduction in gross profit, which was partially offset by the reductions in selling and research and development expenses due to cost containment efforts designed to align with the lower revenues and to fund the facility move which is reflected in the higher general and administrative expenses as noted above.

NET REVENUES AND GROSS PROFIT

The following table presents comparative net revenues and gross profit for our operations:

	2014	2013	Increase (Decrease)
Net Revenues:			
Domestic	$ 20,886,000	$ 23,117,000	$ (2,231,000)
European	5,506,000	5,138,000	368,000
Total	26,392,000	28,255,000	(1,863,000)
Cost of Sales	13,778,000	14,442,000	(664,000)
Gross Profit	$ 12,614,000	$ 13,813,000	$ (1,199,000)
% of Total	47.8%	48.9%	

The net decrease in revenues was primarily attributed to net revenues of $20,886,000 from domestic operations during 2014, compared to net revenues of $23,117,000 during 2013. The $2,231,000 decrease in net revenues from domestic operations was principally due to a reorganization of the salesforce, a relocation of the Miami operations to the Miami Lakes facility in the fourth quarter, and a decrease in instrument orders in the international market. These net decreases in revenues were partially offset by increases in net revenues from the European operations on increased product sales.

The net decrease in gross profit was primarily attributed to gross profit of $9,855,000 from domestic operations in 2014, compared to gross profit of $10,897,000 from domestic operations in 2013. These decreases were primarily related to the decreases in net revenues from these businesses as discussed above. Gross profit as a percentage of net revenues dropped to 47.8% in 2014 from 48.9% in 2013 as a result of the lower volume as well as manufacturing inefficiencies and higher costs due to the facility move.

OPERATING EXPENSES

The following table presents our comparative operating expenses for 2014 and 2013. The percentages below are based on the net revenues in the above table:

	2014	% of Revenue	2013	% of Revenue	Increase (Decrease)
Selling	$ 4,039,000	15.3%	$ 5,309,000	18.8%	$ (1,270,000)
General and Administrative	6,290,000	23.8%	5,547,000	19.7%	743,000
Research and Development	1,412,000	5.4%	1,920,000	6.8%	(508,000)
Total Operating Expenses	$ 11,741,000	44.5%	$ 12,776,000	45.3%	$ (1,035,000)

Total operating expenses decreased $1,035,000 from $12,776,000 in 2013 to $11,741,000 in 2014.

The 24% decrease of $1,270,000 in selling expenses in 2014 compared to 2013 resulted primarily from a decrease in selling expenses of $1,098,000 from domestic operations, which incurred selling expenses of $2,918,000 in 2014 compared to selling expenses of $4,016,000 in 2013. Contributing to the decreases were open sales positions and lower commissions from lower sales in various commissionable categories in the domestic operations.

The 14% increase of $743,000 in general and administrative expenses in 2014, compared to 2013 was primarily due to an increase in general and administrative expenses from domestic operations to $5,482,000 in 2014 from $4,900,000 in 2013. We attribute this increase in general and administrative expenses in domestic operations to moving expenses and additional rent for the Miami Lakes expanded facility as well as higher depreciation from increased fixed assets related to the move and the implementation of a new ERP system.

The 26% decrease of $508,000 in research and development expenses in 2014, compared to 2013 was primarily due to a decrease in research and development activities from the research and development efforts in Italy related to the development of the next generation ELISA platform – LISA XL as we reached the protoype stage of development and lower spending in the domestic operations as we downsized headcount.

INCOME FROM OPERATIONS

Income from operations totaled $873,000 in 2014 as compared to operating income of $1,037,000 in 2013. The decrease in operating income in 2014 as compared to 2013 resulted primarily from the reductions in gross profit, which more than offset the reduction in selling expenses and research and development expenses.

OTHER INCOME (EXPENSE), NET

Other income (expense) totaled a net expense of $307,000 in 2014 as compared to a net expense of $242,000 in 2013. The 2014 balance consists of foreign currency transaction losses of $256,000, interest expense of $38,000 and net other expenses of $12,000. The 2013 balance consists of foreign currency transaction gains of $187,000, interest expense of $122,000, expenses of $211,000 related to the acquisition of Drew Scientific that occurred in October 2012, and net other expenses of $96,000.

INCOME TAX PROVISION

We recorded income tax provisions of $117,000 for 2014 and $119,000 for 2013. 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 $69,000 for both 2014 and 2013 represent the deferred tax provisions in these years relating to domestic tax-deductible goodwill.

See also Note 7, *Income Taxes*, to the Consolidated Financial Statements regarding other tax matters.

NET INCOME

Net income for 2014 was $450,000, compared to net income of $676,000 in 2013. The 33% decrease in net income resulted primarily from a decrease in gross profit of $1,200,000 in 2014 as compared to 2013, and foreign currency transaction losses of $256,000 in 2014 as compared to foreign currency transaction gains of $187,000 in 2013. These reductions were partially offset by the decrease in operating expenses of $1,035,000 in 2014 as compared to 2013, expenses of $211,000 that we incurred in 2013 related to the acquisition of Drew Scientific and higher interest and other expenses incurred during 2013 as compared to 2014. Basic and diluted net income per common share was $0.01 in 2014 as compared $0.02 and $0.01, respectively in 2013.

LIQUIDITY AND CAPITAL RESOURCES

At December 31, 2014, our working capital was $12,133,000 compared to $11,549,000 at December 31, 2013. Cash and cash equivalents totaled $2,548,000 at December 31, 2014 and $4,031,000 at December 31, 2013.

Operating activities

Net cash flows of $538,000 were used in operating activities during 2014 as compared to $875,000 that were used in operating activities during 2013.

Cash used in operating activities of $538,000 during 2014 was the result of the net income of $450,000, offset by an aggregate use of cash in operating assets and liabilities of $1,743,000 and non-cash items of $755,000. The non-cash items include depreciation, amortization of intangible assets, and adjustment to both the allowances for doubtful accounts and inventory obsolescence, non-cash compensation expense and deferred income taxes. Cash used in changes in operating assets and liabilities was due to changes in accounts receivable, inventories, other current assets, deferred liabilities, accounts payable and accrued expenses and other long-term liabilities.

Cash used in operating activities of $875,000 during 2013 was the result of the net income of $676,000, offset by an aggregate use of cash in operating assets and liabilities of $2,770,000 and non-cash items of $1,220,000. The non-cash items include principally depreciation, amortization of intangible assets, noncash compensation, adjustments to each of the allowances for doubtful accounts and inventory obsolescence, and deferred income taxes. Cash used in changes in operating assets and liabilities was due to changes in accounts receivable, inventories, other current assets, deferred liabilities, accounts payable and accrued expenses and other long-term liabilities.

Investing activities

Net cash of $1,249,000 and $572,000 was used in investing activities during 2014 and 2013, respectively. The cash flows relating to investing activities in 2014 were principally for capital expenditures of $889,000 and acquisition of equipment on lease of $253,000 and restricted deposits of $107,000. The cash flows relating to investing activities in 2013 were principally for capital expenditures of $298,000, acquisition of equipment on lease of $217,000, and restricted deposits of $57,000.

Financing activities

Net cash of $425,000 and $1,109,000 was provided by financing activities in 2014 and 2013, respectively. Financing activities during 2014 reflect $390,000 in proceeds from the exercise of stock options and $35,000 in net borrowings under our revolving line of credit. Financing activities during 2013 primarily reflect the draw down of $1,131,000 from our revolving line of credit.

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, 2014, the expected cash flow from operations 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 $1,412,000 during the year ended December 31, 2014 and $1,920,000 for the year ended December 31, 2013 of which our subsidiary, Delta Biologics, billed ERBA Mannheim $579,000 and $896,000 in 2014 and 2013, 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.

For a detailed discussion of related party activities, refer to Note 13, *Related Party Transactions*, to our Consolidated Financial Statements.

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 2014, 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 2014 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, 2014, 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.

RECENTLY ISSUED ACCOUNTING STANDARDS

Refer to Note 3, *Recently Issued Accounting Standards* to the Consolidated Financial Statements regarding recently issued accounting standards applicable to us.

CURRENCY FLUCTUATIONS

For the years December 31, 2014 and 2013, approximately 21% and 18.3%, 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 an increase of approximately $5,600 in net revenues for the year ended December 31, 2014 as compared to the year ended December 31, 2013. 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, 2014 and 2013, 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 7, *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 sheets of ERBA Diagnostics, Inc. (a Delaware corporation) and its subsidiaries (collectively, the "Company") as of December 31, 2014 and 2013, and the related consolidated statements of income and comprehensive income, shareholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2014. 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 audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 consolidated financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of ERBA Diagnostics, Inc. and its subsidiaries as of December 31, 2014 and 2013, and the results of their operations and their cash flows for each for the years in the two-year period ended December 31, 2014, in conformity with accounting principles generally accepted in the United States of America.

/s/ Mayer Hoffman McCann P.C.

Boca Raton, Florida
May 15, 2015

ERBA Diagnostics, Inc. and Subsidiaries
Consolidated Balance Sheets
December 31, 2014 and 2013

	2014	2013
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 2,548,295	$ 4,031,071
Accounts receivable, net	6,414,895	5,546,715
Inventories, net	6,999,335	6,494,173
Related party receivables	1,489,461	1,834,732
Other current assets	1,029,982	395,196
Total current assets	18,481,968	18,301,887
PROPERTY, PLANT AND EQUIPMENT:		
Land	352,957	352,957
Buildings and improvements	3,794,422	3,136,434
Machinery and equipment	4,063,424	3,831,213
Furniture and fixtures	2,048,813	2,216,720
	10,259,616	9,537,324
Less: accumulated depreciation	(8,276,970)	(7,976,121)
Property, plant and equipment, net	1,982,646	1,561,203
OTHER LONG-TERM ASSETS:		
Intangible assets, net	1,165,325	1,480,151
Goodwill	3,494,619	3,494,619
Equipment on lease, net	573,293	586,785
Product license	169,762	226,349
Restricted deposits	311,516	204,686
Other assets	16,656	18,786
Total other long-term assets	5,731,171	6,011,376
Total assets	$ 26,195,785	$ 25,874,466
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 2,399,874	$ 1,953,906
Revolving line of credit	1,939,661	1,904,879
Other accrued expenses	2,009,661	2,894,430
Total current liabilities	6,349,196	6,753,215
OTHER LONG-TERM LIABILITIES:		
Deferred tax liabilities	644,948	576,160
Other long-term liabilities	985,513	1,027,425
Total other long-term liabilities	1,630,461	1,603,585
Total liabilities	7,979,657	8,356,800
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Preferred stock, par value $0.01, authorized 5,000,000 shares, none issued and outstanding in 2014 and 2013	-	-
Common stock, par value $0.01, authorized 100,000,000 shares, issued and outstanding 44,086,009 and 43,658,221 in 2014 and 2013	440,860	436,582
Additional paid-in capital	53,540,057	53,081,370
Accumulated deficit	(35,411,738)	(35,861,343)
Accumulated other comprehensive loss	(353,051)	(138,943)
Total shareholders' equity	18,216,128	17,517,666
Total liabilities and shareholders' equity	$ 26,195,785	$ 25,874,466

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

ERBA Diagnostics, Inc. and Subsidiaries
Consolidated Statements of Income and Comprehensive Income
For the Years Ended December 31, 2014 and 2013

	2014	2013
NET REVENUE	$ 26,391,600	$ 28,255,317
COST OF SALES	13,778,126	14,442,815
Gross profit	12,613,474	13,812,502
OPERATING EXPENSES:		
Selling	4,038,809	5,308,528
General and administrative	6,289,621	5,547,078
Research and development	1,412,077	1,920,171
Total operating expenses	11,740,507	12,775,777
Income from operations	872,967	1,036,725
OTHER INCOME (EXPENSE), NET:		
Interest expense	(38,447)	(121,963)
Unrealized (loss) gain on foreign currency transactions	(256,420)	187,252
Acquisition expenses	-	(211,045)
Other income (expense), net	(11,852)	(96,087)
Total other income (expense), net	(306,719)	(241,843)
Income before provision for income taxes	566,248	794,882
PROVISION FOR INCOME TAXES	(116,643)	(119,054)
Net income	449,605	675,828
OTHER COMPREHENSIVE INCOME (LOSS):		
Foreign currency translation adjustment	(214,108)	375,960
Total comprehensive income	$ 235,497	$ 1,051,788
NET INCOME PER SHARE – Basic	$ 0.01	$ 0.02
NET INCOME PER SHARE – Diluted	$ 0.01	$ 0.01
WEIGHTED AVERAGE SHARES OUTSTANDING:		
Basic	43,882,959	43,658,221
Diluted	54,842,733	48,542,706

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, 2014 and 2013

	Common Stock		Additional Paid-in	Accumulated	Accumulated Other Comprehensive	Total Shareholders'
	Shares	Amount	Capital	Deficit	Loss	Equity
Balances as of December 31, 2012	43,658,221	$ 436,582	$ 52,947,370	$ (36,537,171)	$ (514,903)	$ 16,331,878
Stock compensation expense	-	-	134,000	-	-	134,000
Net income	-	-	-	675,828	-	675,828
Foreign currency translation adjustment	-	-	-	-	375,960	375,960
Balances as of December 31, 2013	43,658,221	436,582	53,081,370	(35,861,343)	(138,943)	17,517,666
Exercise of stock options	427,788	4,278	386,067	-	-	390,345
Stock compensation expense	-	-	72,620	-	-	72,620
Net income	-	-	-	449,605	-	449,605
Foreign currency translation adjustment	-	-	-	-	(214,108)	(214,108)
Balances as of December 31, 2014	44,086,009	$ 440,860	$ 53,540,057	$ (35,411,738)	$ (353,051)	$ 18,216,128

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, 2014 and 2013

	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income	$ 449,605	$ 675,828
Adjustments to reconcile net income to net cash used in operating activities-		
Depreciation and amortization	1,063,423	960,070
Provision for doubtful accounts receivable	(55,345)	39,221
Provision for (reversal of) inventory obsolescence	(393,558)	17,652
Non-cash compensation	72,619	134,000
Deferred income tax provision	68,788	68,788
Changes in operating assets and liabilities:		
Accounts receivable	(913,938)	294,920
Inventories	(290,469)	(584,383)
Other current assets	(652,389)	(179,077)
Accounts payable and accrued expenses	(159,067)	(1,190,856)
Related party receivables	193,479	(1,125,161)
Other long-term liabilities	79,063	13,918
Net cash used in operating activities	(537,788)	(875,080)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Capital expenditures	(889,101)	(297,909)
Restricted deposits	(106,830)	(56,645)
Acquisition of equipment on lease, net	(252,688)	(217,167)
Net cash used in investing activities	(1,248,619)	(571,721)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of stock options	390,345	-
Net proceeds from revolving line of credit	34,782	1,130,707
Capital lease payments	-	(21,947)
Net cash provided by financing activities	425,127	1,108,760
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(121,496)	243,294
NET DECREASE IN CASH AND CASH EQUIVALENTS	(1,482,776)	(94,747)
CASH AND CASH EQUIVALENTS, beginning of year	4,031,071	4,125,818
CASH AND CASH EQUIVALENTS, end of year	$ 2,548,295	$ 4,031,071
SUPPLEMENTAL DISCLOSURES:		
Income taxes paid	$ 69,585	$ 51,609
Interest paid	$ 33,815	$ 28,156

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

1 ORGANIZATION AND OPERATIONS

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

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 in Note 13, *Related Party Transactions*, 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 in Note 13, *Related Party Transactions*, for 600,000 shares of the Company's common stock, ERBA Mannheim now beneficially owns, directly or indirectly, approximately 81.6% of the outstanding shares of the Company's common stock.

2 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 operating subsidiaries: Diamedix Corporation ("Diamedix"), ImmunoVision, Inc. ("ImmunoVision"), Delta Biologicals, S.r.l. ("Delta Biologicals"), Drew Scientific, Inc. ("Drew Scientific") and its subsidiary, JAS Diagnostics, Inc. ("JAS Diagnostics").

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 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.

The allowance for doubtful accounts was $937,578 and $1,064,739 as of December 31, 2014 and 2013, respectively, and activity for the years then ended was as follows:

	2014	2013
Balance as of January 1	$ 1,064,739	$ 995,662
(Reversal) Provision	(55,427)	39,559
Effects of changes in foreign exchange rates	(71,734)	29,518
Balance as of December 31	$ 937,578	$ 1,064,739

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, 2014 and 2013:

	2014	2013
Raw materials	$ 3,292,215	$ 3,123,380
Work-in-process	1,215,178	624,454
Finished goods	2,492,242	2,746,339
Total inventories, net	$ 6,999,635	$ 6,494,173

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 approximately $759,000 and $1,129,000 as of December 31, 2014 and December 31, 2013, respectively.

Property, Plant and Equipment

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

	Years
Buildings and improvements	5-20
Machinery and equipment	3-10
Furniture and fixtures	3-10

Costs of major additions and improvements are capitalized and expenditures for maintenance and repairs which do not extend the life of the assets are expensed. Upon sale or disposition of property, plant and equipment, the cost and related accumulated depreciation is eliminated from the accounts and any resulting gain or loss is credited or charged to operations.

Depreciation expense was approximately $470,000 and $393,000 during the years ended December 31, 2014 and 2013, 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 2, *Summary of Significant Accounting Policies*, below under the heading *Revenue Recognition*), less accumulated amortization, consists of the following as of December 31, 2014 and 2013:

	2014	2013
Equipment on lease, at cost	$ 6,411,565	$ 6,773,917
Less accumulated amortization	5,838,272	6,187,132
	$ 573,293	$ 586,785

Equipment on lease is typically amortized over three or five years. Amortization expense was approximately $226,000 and $214,000 for the years ended December 31, 2014 and 2013, respectively.

Intangible Assets

Intangible assets relate to the acquisition of Drew Scientific, which occurred in October 2012, and consist of the following as of December 31, 2014 and 2013:

	Estimated Remaining Useful Life (Years)	As of December 31, 2014			As of December 31, 2013		
		Gross Amount	Accumulated Amortization	Net Amount	Gross Amount	Accumulated Amortization	Net Amount
Customer relationships	3.8	$ 1,026,532	$ 477,872	$ 548,660	$ 1,026,532	$ 266,957	$ 759,575
Trademarks/Tradenames	9	512,701	115,345	397,356	512,701	64,087	448,614
Patents	6	309,057	89,748	219,309	309,057	53,168	255,889
Lease rights	–	47,140	47,140	–	47,140	31,067	16,073
		$ 1,895,430	$ 730,105	$ 1,165,325	$ 1,895,430	$ 415,279	$ 1,480,151

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

Years Ending December 31,	
2015	$ 303,540
2016	303,540
2017	215,035
2018	91,152
2019	91,152
Thereafter	160,906
	$ 1,165,325

Amortization expense related to the acquired intangible assets for the years ended December 31, 2014 and 2013 amounted to approximately $315,000 and $332,000, respectively.

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 19% for both years, no impairment was recorded for the years ended December 31, 2014 or 2013.

The goodwill of Drew Scientific was also subjected to the annual testing for impairment and its value was determined by the Company with similar significant reliance on the income approach. This approach utilized significant assumptions including a forecasted cash flow period of five years, a long-term annual growth rate 3% and a discount rate of 19% for 2014 and 2013. The market approach was not considered to be as reliable as the income approach due to the difficulty of identifying similar publicly traded companies comparable to Drew Scientific and the stock price volatility in the industry. The Company determined that the income approach is more appropriate, and, based upon the results of the Company's analyses, no impairment was recorded during the years ended December 31, 2014 and 2013.

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, 2014 and 2013, respectively.

Restricted Deposits

Long-term restricted deposits of $311,516 and $204,686 as of December 31, 2014 and 2013, 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 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" 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, 2014 and 2013 were not significant.

The Company recognizes milestone payments when earned, as evidenced by written acknowledgement 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 13, *Related Party Transactions,* the Company entered into a contract research and development agreement with ERBA Mannheim during 2011. Expenses incurred during 2014 and 2013 pursuant to that contract, which approximated the amounts billed to ERBA Mannheim, are included in research and development expenses.

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. The Company recognized an unrealized loss and gain on foreign currency transactions of $256,420 and $187,252 during the years ended December 31, 2014 and 2013, respectively.

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, or BSM. 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, 2014 and 2013.

As of December 31, 2014, the Company had stock-based employee compensation plans as described in Note 10, *Shareholders' Equity.*

Income per Share

Basic income per share excludes any dilution. It is based upon the weighted average number of shares of common stock outstanding during the period. Diluted income 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, 2014, 150,000 shares of common stock underlying stock options were not included in computing diluted income per share because their effects would be anti-dilutive. As of December 31, 2013, 450,000 shares of common stock 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.

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.

3 RECENTLY ISSUED ACCOUNTING STANDARDS

In July 2013, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2013-11 ("ASU 2013-11"), "Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists". ASU 2013-11 states that an unrecognized tax benefit, or a portion of an unrecognized tax benefit, should be presented in the financial statements as a reduction to a deferred tax asset for a net operating loss ("NOL") carryforward, a similar tax loss, or a tax credit carryforward. The exception to this treatment is as follows: to the extent an NOL carryforward, a similar tax loss, or a tax credit carryforward is not available at the reporting date or if the entity is not required to use and does not intend to use the deferred tax asset, then the unrecognized tax benefit should be presented in the financial statements as a liability and should not be combined with deferred tax assets. ASU 2013-11 does not require any additional recurring disclosures. Effective January 1, 2014, the Company adopted ASU 2013-11. There was no impact to the Company's consolidated financial statements as a result of the adoption of ASU 2013-11.

In April 2014, the FASB issued ASU No. 2014-08 ("ASU 2014-08"), "Presentation of Financial Statements (Topic 205) and Property, Plant, and Equipment (Topic 360): Reporting Discontinued Operations and Disclosures of Disposals of Components of an Entity." This update raises the threshold for a disposal to qualify as a discontinued operation and requires new disclosures for discontinued operations and disposals that do not meet the definition of a discontinued operation. ASU 2014-08 is effective prospectively for fiscal years, and interim periods within those years, beginning after December 15, 2014. Early adoption of ASU 2014-08 is permitted, but only for disposals or assets held for sale that have not been reported in previously issued (or available to be issued) financial statements. The Company is currently evaluating the impact of the adoption of ASU 2014-08 on its consolidated financial statements.

In May 2014, the FASB issued ASU No. 2014-09 ("ASU 2014-09"), "Revenue from Contracts with Customers (Topic 606)." ASU 2014-09 provides a single comprehensive model for entities to use in accounting for revenue arising from contracts with customers and supersedes most current revenue recognition guidance, including industry specific guidance. ASU 2014-09 will require entities to recognize revenue when it transfers promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. ASU 2014-09 is effective for annual reporting periods beginning after December 31, 2016, including interim periods. The Company will have the option to apply the provisions of ASU 2014-09 either retrospectively to each reporting period presented, or retrospectively with the cumulative effect of applying this standard at the date of initial application. Early adoption is not permitted. Recent tentative decisions by the FASB may delay the effective date of this ASU and some of its other provisions. The Company is currently evaluating the method and impact of the adoption of ASU 2014-09 will have on the Company's consolidated financial statements.

In June 2014, the FASB issued ASU No. 2014-12 ("ASU 2014-12"), "Compensation – Stock Compensation (Topic 718) - Accounting for Share-Based Payments When the Terms of an Award Provide That a Performance Target Could Be Achieved after the Requisite Service Period." ASU 2014-12 requires that a performance target that affects vesting and which could be achieved after the requisite service period be treated as a performance condition. ASU 2014-12 is effective for fiscal years beginning after December 15, 2015, and for interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of the adoption of ASU 2014-12 on its consolidated financial statements.

In August 2014, the FASB issued ASU No. 2014-15 ("ASU 2014-15"), "Presentation of Financial Statements-Going Concern (Subtopic 205-40) – Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern." ASU 2014-15 requires a Company's management to evaluate, at each reporting period, whether there are conditions or events that raise substantial doubt about the entities ability to continue as a going concern within one year after the date the financial statements are issued and provide related disclosures. ASU 2014-15 is effective for the annual period ending after December 15, 2016, and for annual periods and interim periods thereafter. The Company is currently evaluating the impact of the adoption of ASU 2014-15 on its consolidated financial statements.

In January 2015, the FASB issued ASU 2015-01, "Income Statement – Extraordinary and Unusual Items (Subtopic 225-20): Simplifying Income Statement Presentation by Eliminating the Concept of Extraordinary Items," which changed the requirements for reporting extraordinary and unusual items in the income statement. The update eliminates the concept of extraordinary items. The presentation and disclosure guidance for items that are unusual in nature or occur infrequently will be retained and will be expanded to include items that are both unusual in nature and infrequently occurring. A reporting entity may apply the amendments prospectively or retrospectively to all periods presented in the financial statements. The guidance will be effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted provided that the guidance is applied from the beginning of the fiscal year of adoption. The adoption of this newly issued guidance is not expected to have an impact to the Company's consolidated financial statements.

In February 2015, the FASB issued ASU 2015-02, "Consolidations (Topic 225-20): Amendments to the Consolidation Analysis," which affects current consolidation guidance. The guidance changes the analysis that a reporting entity must perform to determine whether it should consolidate certain types of legal entities. This guidance must be applied using one of two retrospective application methods and will be effective for fiscal years, and for interim periods within those fiscal years, beginning after December 15, 2015. Early adoption is permitted, including adoption in any interim period. The Company is currently evaluating the impact, if any, of the adoption of this newly issued guidance to its consolidated financial statements.

In April 2015, the FASB issued ASU 2015-03, "Interest – Imputation of Interest (Topic 225-20): Simplifying the Presentation of Debt Issue Costs," that simplifies the presentation of debt issuance costs. The guidance requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The recognition and measurement guidance for debt issuance costs are not affected by these amendments. This guidance should be applied on a retrospective basis, wherein the balance sheet of each individual period presented should be adjusted to reflect the period-specific effects of applying the new guidance. The guidance will be effective for financial statements issued for fiscal years beginning after December 15, 2015, and interim periods within those fiscal years. Early adoption is permitted for financial statements that have not been previously issued. The Company is currently evaluating the impact, if any, of the adoption of this newly issued guidance to its consolidated financial statements.

4 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, 2014 and 2013 are as follows:

	Gross Carrying Amount	Accumulated Impairment	Net Book Value
ImmunoVision	$ 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

5 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, 2013, the balance of 100,000 Euro (equivalent to approximately $132,000) was offset against 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.

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.

While the license is perpetual, the Company believes that the expected economic useful life of the license will be five years after the Company began to utilize the licensed technology for its intended purpose. Sales commenced in January 2013, at which time amortization of the license began. The Company amortized approximately $57,000 related to the license during both of the years ended December 31, 2014 and 2013. The Company will amortize approximately $57,000 for each of the next three years related to the product license.

6 CONCENTRATION OF CREDIT RISK

The Company performs periodic credit evaluations of its customers' financial condition and provides allowances for doubtful accounts as required. The Company 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 fiscal and debt crisis the Italian government is facing. As of December 31, 2014 and 2013, Delta Biologicals' accounts receivable, primarily due from Italian companies, were approximately $2,120,000 and $4,647,000, respectively. Amounts due from hospitals and laboratories controlled by the Italian government as of December 31, 2014 and 2013 were approximately $865,000 and $1,700,000, respectively, which accounted for approximately 15% and 24%, respectively, of the Company's consolidated net accounts receivable. Delta Biologicals recognized revenues during the years ended December 31, 2014 and 2013 in the amount of approximately $5,540,000 and $5,138,000, respectively, which represented approximately 21% and 18%, 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, 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 of approximately $1,700,000 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. The Company's cash balances exceed federally insured limits by approximately $610,000 as of December 31, 2014.

7 INCOME TAXES

The provision for income taxes consists of the following for the years ended December 31, 2014 and 2013:

	2014	2013
Current:		
Domestic	$ -	$ -
Foreign	47,855	50,266
Deferred:		
Domestic	68,788	68,788
Total	$ 116,643	$ 119,054

The components of income (loss) before income taxes are as follows for the years ended December 31, 2014 and 2013:

	2014	2013
Domestic	$ 606,860	$ 1,056,504
Foreign	(40,612)	(261,622)
Total	$ 566,248	$ 794,882

The significant components of the net deferred income tax asset balances are as follows as of December 31, 2014 and 2013:

	2014	2013
Current:		
Accounts receivable allowances	$ 290,798	$ 301,628
Reserves and accruals	276,250	248,119
Capitalized inventory costs	256,990	102,742
Other	608	608
Valuation allowance	(824,646)	(653,097)
Deferred income taxes	-	-
Long-term:		
Depreciation and basis differences on tangible and intangible assets	463,988	396,524
Stock based compensation	438,946	410,987
Other	338	(53,372)
Foreign net operating losses	1,113,688	1,005,901
Domestic net operating losses	6,714,422	7,063,328
Valuation allowance	(8,731,382)	(8,823,368)
Net deferred tax asset	$ -	$ -

The net deferred income tax liability balance consists of tax deductible goodwill of $644,948 and $576,160, as of December 31, 2014 and 2013, 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, 2014 and 2013, the Company had no net domestic deferred tax assets. As of December 31, 2014 and 2013, the Company had net deferred tax liabilities of $644,948 and $576,160, respectively, relating to tax deductible goodwill which is not expected to reverse in the foreseeable future. Additionally, as of December 31, 2014 and 2013, the Company also had no net foreign deferred tax asset, as a full valuation allowance was provided. Future changes in the estimated net realizable value of the deferred tax assets or deferred tax liabilities could cause the provision for income taxes to vary significantly from period to period.

A reconciliation of the difference between the expected provision for income taxes using the statutory U.S. Federal tax rate and the Company's actual provision is as follows for the years ended December 31, 2014 and 2013:

	2014	2013
Provision (benefit) for income taxes at U.S. Federal statutory rate of 35%	$ 198,268	$ 298,591
Change in valuation allowance (excluding portion relating to stock options)	79,652	(328,498)
Foreign tax rate differential	(183,893)	63,480
Global permanent differences	22,705	85,481
Provision for income taxes	$ 116,643	$ 119,054

Domestic net operating losses generated by the Company total $17,215,000 as of December 31, 2014 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 $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 ownership change. The limitations of these net operating loss carryforwards did not impact the Company's results for the years ended December 31, 2014 or 2013.

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, 2014, the Company's Federal income tax returns for the years 2011 through 2014 and, with respect to foreign operations, the Italian income tax returns for 2010 through 2014 remain subject to examination. Although the Company's Federal income tax returns from 2002 through 2010 are not generally open to examination, the Company remains subject to adjustments in these years to the extent of the net operating losses being carried forward from 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, 2014 and 2013, 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.

8 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. The Company did not make any matching contributions during the years ended December 31, 2014 and 2013.

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; during the year ended December 31, 2013, this plan was merged into the Company's 401(k) employee savings plan.

Drew Scientific also had a defined contribution retirement plan. This plan had continued subsequent to October 3, 2012 and was 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 Drew Scientific's United Kingdom facility.

9 ACCRUED EXPENSES AND OTHER LONG-TERM LIABILITIES

Accrued expenses consist of the following as of December 31, 2014 and 2013:

	2014	2013
Payroll costs	$ 397,409	$ 645,943
Taxes, primarily VAT	886,490	800,756
Professional fees	121,098	755,770
Royalties	67,270	65,270
Deferred revenue	188,009	249,159
Other	349,385	377,532
Balance as of December 31	$ 2,009,661	$ 2,894,430

Other long-term liabilities of $985,513 as of December 31, 2014, and $1,027,425 as of December 31, 2013, 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.

10 SHAREHOLDERS' EQUITY

Preferred and Common Stock

The Company has authorized 5,000,000 shares of preferred stock, par value $0.01 per share, of which none were designated or outstanding at December 31, 2014 and 2013, respectively.

The Company has authorized 100,000,000 shares of common stock, par value $0.01 per share, of which 44,086,009 and 43,658,221 shares were outstanding at December 31, 2014 and 2013, respectively. As of December 31, 2014, ERBA Mannheim, the Company's majority stockholder, owned, directly or indirectly, approximately 81.6% of the outstanding shares of the Company's common stock.

In previous years, the Company entered into various agreements and transactions with its majority stockholder. See Note 13, *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 ended December 31, 2014 and 2013, the Company did not repurchase any shares of its common stock. The total number of shares of common stock repurchased by the Company since the inception of its repurchase program is 1,184,573.

Equity Incentive Plans

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

The Company's Performance Plan was created on September 30, 1999 upon approval by the Board of Directors and stockholders of b2bstores.com. The Performance Plan authorized the grant of up to 2,000,000 shares of common stock of the Company to key employees, officers, directors and consultants. As a result of the approval of the 2009 Plan, the Company will not grant any additional awards under the Performance Plan.

Options granted under these option plans were granted at an option exercise price equal to or greater than the closing market value of the stock on the date of the grant and with vesting, primarily for Company employees, ranging from all at once to equal annual amounts over a four year period, and, for non-employee directors, immediately. The options generally have a term of 10 years.

The Company accounts for its stock-based compensation plans in accordance with ASC 718-10, Compensation – Stock Compensation. Under the provisions of ASC 718-10, the fair value of each stock option is estimated on the date of grant using a BSM option-pricing formula, and amortizing that value to expense over the expected performance or service periods using the straight-line attribution method. The weighted average values of the assumptions used to value the options granted in the year ended December 31, 2014 were as follows: expected term of 10 years, expected volatility of 100.48%, risk-free interest rates of 0.3%, and expected dividend yield of 0%. The weighted average values of the assumptions used to value the options granted in the year ended December 31, 2013 were as follows: expected term of 10 years, expected volatility of 100.39%, risk-free interest rates of 0.3%, and expected dividend yield of 0%.

The Company recorded stock-based compensation expense of approximately $73,000 and $134,000 for the years ended December 31, 2014 and 2013, respectively. As of December 31, 2014, unrecognized compensation costs totaled $37,000. As of December 31, 2013, all outstanding options were vested and therefore there was no unrecognized compensation cost at that time. No windfall tax benefits were recognized during the years ended December 31, 2014 or 2013.

The following table summarizes the stock option activity (both outstanding and exercisable) as of December 31, 2014 and 2013 and changes during the years ended December 31, 2014 and 2013 under the Performance Plan and the 2009 Plan:

	Number of Shares	Weighted Average Exercise Price
Balance as of December 31, 2012	1,120,870	$ 1.28
Granted	100,000	$ 1.52
Forfeited	(50,000)	$ 0.65
Outstanding as of December 31, 2013 (all vested and exercisable)	1,170,870	$ 1.33
Granted	65,000	$ 1.74
Exercised	(427,788)	$ 0.91
Outstanding as of December 31, 2014	808,082	$ 1.59
Exercisable as of December 31, 2014	773,082	$ 1.60
Vested or expected to vest as of December 31, 2014	808,082	$ 1.59

The following table summarizes information about our stock options at December 31, 2014:

	Outstanding Options			Exercisable Stock Options	
Range of Exercise Prices	**Shares**	**Weighted-Average Remaining Contractual Life in Years**	**Weighted-Average Exercise Price**	**Shares**	**Weighted-Average Exercise Price**
$0.00 to $0.50	75,000	4.23	$ 0.48	75,000	$ 0.48
$0.51 to $0.75	253,082	5.02	0.58	253,082	0.58
$0.76 to $1.00	100,000	4.52	0.96	100,000	0.96
$1.01 to $1.50	50,000	3.73	1.20	50,000	1.20
$1.51 to $3.00	180,000	6.01	1.60	145,000	1.57
$3.01 to $5.00	150,000	0.52	4.37	150,000	4.37
Total stock options	808,082	4.19	1.59	773,082	1.60

As of December 31, 2014, 3,290,318 shares were available for issuance under our plans.

The intrinsic value of a stock option is the amount by which the fair value of the underlying stock exceeds the exercise price of the option. The fair value of the Company's common stock was $3.17 at December 31, 2014 based on the closing price on the NYSE MKT. As of December 31, 2014, the aggregate intrinsic value of options outstanding, exercisable and vested or expected to vest was $1,459,144, $1,408,494 and $1,459,144, respectively.

As of December 31, 2014, the weighted average remaining contractual life for exercisable options is 3.95 years, and for options vested or expected to vest is 4.19 years.

During the year ended December 31, 2014, several members of the Company's Board of Directors and a former executive officer of the Company exercised 427,788 stock options at a weighted average exercise price of $0.91 for total cash proceeds of approximately $390,000. The intrinsic value of the stock options exercised during the year ended December 31, 2014 was approximately $822,000. There were no stock option exercises during the year ended December 31, 2013.

On May 22, 2014, the Company granted to its independent directors stock options to purchase an aggregate of 30,000 shares of the Company's common stock at an exercise price of $1.76 per share. The options vested immediately and expire on May 21, 2024. The fair market value of such stock options was $1.57 per stock option based on the BSM.

On June 1, 2014, the Company granted to an executive officer stock options to purchase 25,000 shares of the Company's common stock at an exercise price of $1.76 per share. The options have a one year vesting period and expire on May 31, 2024. The fair market value of such stock options was $1.57 per stock option based on the BSM.

On June 6, 2014, the Company granted to an executive officer stock options to purchase 10,000 shares of the Company's common stock at an exercise price of $1.63 per share. The options have a three year vesting period and expire on May 31, 2024. The fair market value of such stock options was $1.45 per stock option based on the BSM.

11 SEGMENT INFORMATION

The Company's management reviews financial information, allocates resources and manages its business by geographic region. The domestic region, which includes corporate expenditures, contains the Company's subsidiaries in the United States. The European region contains Delta Biologicals, the Company's subsidiary located in Italy, and, from and after the acquisition date of October 3, 2012 and until late March 2013, 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, goodwill, depreciation and amortization, and capital expenditures by region for the years ended December 31, 2014 and 2013:

	Domestic	European	Eliminations	Total
December 31, 2014:				
External net sales	$ 20,886,143	$ 5,505,457	$ -	$ 26,391,600
Intercompany sales	410,508	34,699	(445,207)	-
Net revenue	$ 21,296,651	$ 5,540,156	$ (445,207)	$ 26,391,600
Income (loss) from operations	$ 903,122	$ (30,155)	$ -	$ 872,967
Assets	$ 40,789,392	$ 5,417,909	$ (20,011,516)	$ 26,195,785
Goodwill	$ 3,494,619	$ -	$ -	$ 3,494,619
Depreciation and amortization	$ 879,113	$ 184,310	$ -	$ 1,063,423
Capital Expenditures	$ 888,237	$ 864	$ -	$ 889,101
December 31, 2013:				
External net sales	$ 23,117,502	$ 5,137,815	$ -	$ 28,255,317
Intercompany sales	488,764	19,615	(508,379)	-
Net revenue	$ 23,606,266	$ 5,157,430	$ (508,379)	$ 28,255,317
Income (loss) from operations	$ 1,137,515	$ (100,790)	$ -	$ 1,036,725
Assets	$ 40,287,271	$ 6,047,420	$ (20,460,225)	$ 25,874,466
Goodwill	$ 3,494,619	$ -	$ -	$ 3,494,619
Depreciation and amortization	$ 747,718	$ 212,352	$ -	$ 960,070
Capital Expenditures	$ 275,592	$ 22,317	$ -	$ 297,909

12 COMMITMENTS AND CONTINGENCIES

Leases

As of December 31, 2014, 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 $146,000 as of December 31, 2014). 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 expansion premises, as follows for each of the succeeding five years: 2015, $401,280; 2016, $417,331; 2017, $434,024; 2018, $451,386; and 2019 $469,441. The amended lease also provides for one five-year renewal option at a market rental rate.

Drew Scientific also had a lease agreement, which commenced on December 15, 2012, for office and warehouse space in Waterbury, Connecticut. The lease expired on December 31, 2013. Drew Scientific continues to lease the space on a month to month basis.

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

Aggregate rent expense under all operating leases for the years ended December 31, 2014 and 2013 totaled approximately $940,000 and $735,000, 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, 2014 are as follows:

Years Ending December 31,		
2015	$	817,000
2016		654,000
2017		539,000
2018		451,000
2019		469,000
Total minimum lease payments	$	2,930,000

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 agreement 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 was depreciated over its estimated productive life (cost of $222,000, net of accumulated depreciation of $91,000). Depreciation of $28,000 in the year ended December 31, 2013 was included in cost of sales. The lease agreement expired in March 2013. The Company continued to lease the equipment upon the maturity of the lease agreement under an operating lease for monthly lease payments of approximately $7,000. The Company retained ownership of the equipment in August 2014. There was no capital lease obligation as of December 31, 2013. Interest expense for the year ended December 31, 2013 was approximately $15,000.

Purchase Commitments

In November 2005 and as amended in February 2013, Drew Scientific entered into a Development and Supply Agreement with a foreign third party to develop and manufacture diagnostic instruments for various analytical uses, including hematology. Beginning in the year ended December 31, 2013, the Development and Supply Agreement requires Drew Scientific to make minimum annual purchases of 500 instruments at a fixed per unit price. However, this price is subject to an upward sliding scale in the event Drew Scientific purchases less than the minimum 500 instruments per year. During each of the years ended December 31, 2014 and 2013, Drew Scientific purchased less than the minimum 500 instruments, but the foreign third party has allowed Drew Scientific to carry forward the shortages of approximately $300,000 into 2015 and did not apply the higher per unit price. The Development and Supply Agreement expires in December 2015.

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.

Other Matters

Effective June 1, 2014, the Company entered into an Employment Agreement with Mohan Gopalkrishnan setting forth the terms and conditions upon which Mr. Mohan shall serve as Chief Executive Officer of the Company. Pursuant to the Employment Agreement, which has a term of two years, the Company has the right to terminate the Employment Agreement, and Mr. Mohan's employment thereunder, for any reason or for no reason, including, without limitation, without Cause by providing Mr. Mohan with at least ninety days prior written notice. The Company also has the right to terminate the Employment Agreement, and Mr. Mohan's employment thereunder, for Cause.

13 RELATED PARTY TRANSACTIONS

Certain Relationships and Related Transactions

During the years ended December 31, 2014 and 2013, the Company sold products to Transasia, and a subsidiary of ERBA Mannheim, for a total amount of approximately $2,375,000 and approximately $606,000 respectively.

During the year ended December 31, 2014, the Company began to incur management fees from ERBA Mannheim related to the management of global trade conferences and distributors in European, North African and Asian countries. During the year ended December 31, 2014, the Company incurred approximately $285,000 in such management fees to ERBA Mannheim.

During 2011, Delta Biologicals entered into a contract research and development agreement with ERBA Mannheim, as amended. Delta Biologicals incurred expenses related to the research and development mentioned above which were billed to ERBA Mannheim for reimbursement. For the years ended December 31, 2014 and 2013, contract research and development revenue under the agreement approximated Euro 436,000 (equivalent to approximately $579,000) and Euro 675,000 (equivalent to approximately $896,000), respectively.

The Company had net accounts receivable from ERBA Mannheim, Transasia and related subsidiaries of $1,489,000 and $1,835,000 as of December 31, 2014 and 2013, respectively, related to the above transactions and receivables from the sale of products and the reimbursement of various expenditures incurred on behalf of ERBA Mannheim.

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 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) plus additional material costs, in seven monthly installments of Euro 50,000 from December 2012 through June 2013, for certain research and development endeavors. On July 24, 2013, JAS Diagnostics and Erba Diagnostics France mutually terminated the agreement above and Erba Diagnostics France agreed to refund to JAS Diagnostics all amounts paid under the agreement within 90 days. The Company continued to pay for the research and development costs through October 2013. The Company incurred total research and development costs of approximately $913,000, all of which were reimbursed by Erba Diagnostics France during the year ended December 31, 2013. The reimbursed research and development costs were recognized as a reduction to research and development expense included in the 2013 consolidated statement of operations.

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 66-2/3% 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.

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, 2014 and 2013. As of December 31, 2014 and 2013, 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. The Company used all of the proceeds of the Second Closing to consummate the acquisition of Drew Scientific.

Other Transactions

During the year ended December 31, 2013, ImmunoVision paid $10,000 to John B. Harley, M.D., Ph.D., who at the time was a member of the Company's Board of Directors, under that certain oral consulting agreement between Dr. Harley, and ImmunoVision pursuant to which Dr. Harley was paid $2,000 per month in consideration for his provision of technical guidance and business assistance to the subsidiary on an as-needed basis. The oral consulting agreement ended in May 2013.

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 years ended December 31, 2014 and 2013, the Company paid $10,000 under such royalty 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.

14 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 "CNB Line of Credit"). As described below, on March 1, 2013, Diamedix closed down the CNB Line of Credit and the Company entered into a loan agreement with Citibank, N.A. ("Citibank"). Amounts outstanding under the CNB 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. The payoff amount at closing was $975,000.

On March 1, 2013, the Company entered into a Business Loan Agreement and Promissory Note with Citibank, which provided for a secured, revolving credit facility of up to $2,000,000 (the "Old Citibank Line of Credit"). Amounts outstanding under the Old Citibank Line of Credit accrued interest at an annual rate equal to the 30-day LIBOR plus 1.75% (1.91% at December 31, 2014) and was to become due and payable on December 31, 2014, but was temporarily extended.

As of December 31, 2014 and 2013, approximately $1,940,000 and $1,905,000, respectively, was outstanding under the Old Citibank Line of Credit.

On March 25, 2015, the Company entered into a new Business Loan Agreement and Promissory Note with Citibank which replaced the previous facility, as further described in Note 15, *Subsequent Events*.

15 SUBSEQUENT EVENTS

On March 25, 2015, our wholly-owned subsidiary located in Miami Lakes, Florida – Diamedix – entered into a Purchase and Sale Agreement with Joe Management LLC, as buyer, for the sale of the real property owned by Diamedix located at 2115, 2140, 2141, 2150, 2155, 2160 North Miami Avenue and 38 NW 22nd Street, in Miami, Florida, and all improvements thereon, or collectively, the Property. The purchase price for the Property is $23,000,000. As of December 31, 2014, the net book value of the land, buildings and improvements being sold was approximately $0.4 million.

The Purchase and Sale Agreement provides for a 45-day examination period, during which the buyer has the right to conduct a due diligence investigation of the Property and terminate the Purchase and Sale Agreement in its sole and absolute discretion. While the Purchase and Sale Agreement is binding upon Diamedix, the buyer, in its sole and absolute discretion, may terminate the Purchase and Sale Agreement during the 45-day examination period, in which case our sale of the Property would not be consummated. On May 8, 2015, the buyer and Diamedix amended the Purchase and Sale Agreement to extend the examination period to June 19, 2015. The Purchase and Sale Agreement provides for the consummation of the purchase and sale of the property to occur within 60 days after the expiration of the extended examination period.

On March 25, 2015, the Company entered into a new Business Loan Agreement and Promissory Note with Citibank, which provides for a secured, revolving credit facility of up to $3,500,000 (the "New Citibank Line of Credit"). The New Citibank Line of Credit has replaced the Old Citibank Line of Credit, which is no longer outstanding. Amounts outstanding under the New Citibank 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 February 29, 2016, 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 is 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.

Amounts outstanding under the New Citibank 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, Drew Scientific and JAS Diagnostics. In addition, each of Diamedix, ImmunoVision, Drew Scientific and JAS Diagnostics has guaranteed the repayment of amounts drawn on the New Citibank Line of Credit. Further, Transasia, the indirect parent company of the Company, has also guaranteed the repayment of amounts drawn on the New Citibank Line of Credit.

Amounts outstanding under the New Citibank Line of Credit are also collateralized by the Company's pledge of up to sixty-six percent (66%) of the total combined voting power of all classes of capital stock and other equity interests entitled to vote of Delta, the Company's wholly-owned subsidiary located in Italy.

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. Based upon that evaluation, our management concluded that our internal control over financial reporting was not effective as of December 31, 2014, 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

We have implemented accounting systems, as well as standards, policies and procedures, at Drew Scientific and JAS Diagnostics, in an effort to ensure that we have in place appropriate internal control over financial reporting at Drew Scientific and JAS Diagnostics. Additionally, our remediation efforts are ongoing to address the material weakness as described above. Except as set forth in the preceding sentences with respect to 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, 2014 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

The following table sets forth information with respect to our directors and our executive officers as of May 8, 2015.

Name	Age	Position
Suresh Vazirani	65	Executive Chairman of the Board of Directors
Mohan Gopalkrishnan	60	Chief Executive Officer
Ernesina Scala	53	Chief Financial Officer
Kishore “Kris” Dudani	60	Director
Philippe Gadal, Pharm.D.	58	Director
Gerald E. Gallwas	78	Director
David M. Templeton	62	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 May 8, 2015. 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. He has also served as the Statutory Body of Erba Lachema s.r.o, an in vitro diagnostics company headquartered in Czech Republic, since 2010 and as the Chairman of the Board of Directors of Erba Diasis Diagnostik Sistemler Sanavi Ve Ticaret Anonim Sirketi, an in vitro diagnostics company headquartered in Turkey, since 2011. As described above, ERBA Mannheim beneficially owns, directly or indirectly, approximately 81.6% 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.

Mohan Gopalkrishnan has served as our Chief Executive Officer since June 2014. In October 2012, Mr. Mohan joined our company as the Vice President – Operations. Prior to joining our company, Mr. Mohan spent 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.

Ernesina Scala has served as our Chief Financial Officer since May 1, 2015. Prior to joining our company, Ms. Scala has over 20 years' experience in finance and accounting. From 2002 until 2014, Ms. Scala was employed at Tyco International Ltd. ("Tyco") and held various senior finance and accounting positions, most recently as Senior Director of Finance and Chief Financial Officer Latin America. Prior to Tyco, Ms. Scala was the Director of Consolidation and SEC Reporting for Sensormatic Electronics Corporation, which was acquired by Tyco. Ms. Scala began her career at Ernst & Young.

Kishore "Kris" Dudani has served as a director on the Board of Directors since September 2010. From 2004 until his retirement in May 2014, Mr. Dudani 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 U.S. 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.

David M. Templeton has served as a director on the Board of Directors since September 2010. Mr. Templeton has served as the President of Global Vet, a veterinary diagnostics 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, 2014.

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.

ITEM 11. EXECUTIVE COMPENSATION

Compensation of Named Executive Officers

Summary Compensation Table – 2014

The following table sets forth certain summary information concerning compensation which, during the fiscal years ended December 31, 2014 and 2013, we paid or accrued to or on behalf of (i) each individual serving or acting as the our principal executive officer during the fiscal year ended December 31, 2014, and (ii) the only other individual serving as an executive officer at December 31, 2014 (collectively, the "Named Executive Officers").

Name and Principal Position	Year	Salary	Bonus	Stock Awards	Option Awards(4)	Non-Equity Incentive Plan Compensation	Change in Pension Value and Nonqualified Deferred Compensation Earnings	All Other Compensation	Total
Mohan Gopalkrishnan, (1)	2014	$199,702	$ 5,000		$ 39,140				$243,842
Chief Executive Officer	2013	$150,000	-	-	-	-	-	-	$150,000
Sanjiv Suri,(2)	2014	-	-	-	-	-	-	-	-
Former Interim	2013	-	-	-	-	-	-	-	-
Chief Executive Officer									
Prakash Patel, (3)	2014	$ 97,523	$ 6,375		$ 14,500				$118,398
Former Controller	2013	$ 47,404	-	-	-	-	-	-	$ 47,404

(1) Mr. Mohan has served as our Chief Executive Officer since June 1, 2014. In October 2012, Mr. Mohan joined our company as the Vice President – Operations. On May 31, 2014, Mr. Mohan entered into an employment agreement with us, which became effective as of June 1, 2014. The terms of Mr. Mohan's employment agreement are described under "Potential Payments upon Termination or Change-in-Control" below.

(2) Mr. Suri resigned effective as of June 1, 2014. Prior to his resignation, Mr. Suri served as our Interim Chief Executive Officer from August 1, 2013 until June 1, 2014. Prior to August 2013, Mr. Suri was not employed by us. Mr. Suri's employment by us was "at-will" and without any employment agreement, and he did not receive any compensation from us for his service as our Interim Chief Executive Officer.

(3) Mr. Patel resigned effective as of April 30, 2015. Prior to his resignation, Mr. Patel served as our Controller since June 2014, and has been with our company since June 2013. Prior to June 2013, Mr. Patel was not employed by us and, accordingly, he did not receive any compensation from us prior to June 2013. On June 6, 2014, Mr. Patel entered into an employment agreement with us, which became effective as of June 1, 2014, and which terminated on April 30, 2015, the effective date of his resignation. The terms of Mr. Patel's employment agreement are described under "Potential Payments upon Termination or Change-in-Control" below.

(4) Represents the aggregate grant date fair value of option awards calculated in accordance with Codification Topic 718, *Compensation – Stock Compensation*. Assumptions used in the calculation of these amounts are included in Note 10 to our Consolidated Financial Statements, *Shareholders' Equity*.

Outstanding Equity Awards at Fiscal Year-End – 2014

The following table sets forth certain information regarding equity-based awards held by the Named Executive Officers as of December 31, 2014.

	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
Mohan Gopalkrishnan	-	25,000(2)	-	$ 1.76	05/31/2024
Prakash Patel(1)	-	10,000(3)	-	$ 1.63	05/31/2024

(1) These options are included in this table because Mr. Patel is a Named Executive Officer. Subsequent to December 31, 2014, these options terminated upon the effective date of Mr. Patel's resignation.

(2) All of these options become fully exercisable on June 1, 2015.

(3) All of these options would have become fully exercisable on May 31, 2017.

Potential Payments upon Termination or Change-in-Control

Employment Agreement with Mohan Gopalkrishnan. On May 31, 2014, we entered into an employment agreement with Mohan Gopalkrishnan to serve as our Chief Executive Officer, which became effective on June 1, 2014. The employment agreement has a term of two years. Under the employment agreement, Mr. Mohan will be paid an annual base salary of $230,000. The employment agreement also provides that Mr. Mohan will be eligible to receive an annual cash bonus of us to 30% of his annual base salary, upon the achievement of company-wide financial performance targets and personal performance goals as set by the Executive Chairman of the Board. Mr. Mohan received a $5,000 annual cash bonus during 2014. The employment agreement also provides that Mr. Mohan will be eligible to receive equity compensation under our equity compensation plans, including, without limitation, a grant, on the effective date of the employment agreement, of options to purchase 25,000 shares of our common stock, with full vesting after one year, and a grant, on the first anniversary of the effective date of the employment agreement, of options to purchase 25,000 shares of our common stock, with full vesting after one year. In addition, under the employment agreement, we are required to reimburse Mr. Mohan for business expenses incurred by him in accordance with our policies and procedures for expense reimbursement. Upon the termination of the employment agreement by us with "Cause" (as defined in the employment agreement) or upon Mr. Mohan's resignation other than for "Good Reason" (as defined in the employment agreement), Mr. Mohan will be entitled to receive all base salary compensation which has been fully earned but has not yet been paid to him, and all of Mr. Mohan's unvested equity based awards will be forfeited. Upon the termination of the employment agreement as a result of Mr. Mohan's "Disability" (as defined in the employment agreement) or death, Mr. Mohan or his estate, as the case may be, will be entitled to receive all base salary and annual cash bonus compensation which has been fully earned but has not yet been paid to him and all business expenses incurred by him which has not yet been reimbursed (such compensation, collectively, the "Mohan Accrued Compensation") and the continuation of his base salary for a period of 90 days. Upon the termination of the employment agreement by us without "Cause" or upon Mr. Mohan's resignation for "Good Reason," Mr. Mohan will be entitled to receive the Mohan Accrued Compensation and the continuation of his base salary for the remainder of the term of the employment agreement, if any. In the case of the termination of the employment agreement by us without "Cause" or upon Mr. Mohan's resignation for "Good Reason," for the remainder of the term of the employment agreement, if any, or in the case of the termination of the employment agreement as a result of Mr. Mohan's "Disability," for a period of 90 days, we, at our sole expense, will maintain in full force and effect for the continued benefit of Mr. Mohan, his spouse and his minor children, all welfare benefit plans or programs maintained by us, including, without limitation, all medical, hospitalization, dental, disability, accidental death and dismemberment and travel accident plans and programs, in which Mr. Mohan or his spouse or his minor children were participating. The employment agreement also includes non-competition, non-solicitation, anti-raiding, non-disparagement and non-disclosure covenants by Mr. Mohan.

Employment Agreement with Prakash Patel. On June 6, 2014, we entered into an employment agreement with Prakash Patel to serve as our Controller, which became effective on June 1, 2014. The employment agreement was terminated on April 30, 2015, the effective date of Mr. Patel's resignation. The employment agreement did not have a term, as there was no fixed duration for Mr. Prakash's employment as Controller, and Mr. Prakash's employment by us under the employment agreement was "at-will." Under the employment agreement, Mr. Patel was paid an annual base salary of $105,000. The employment agreement also provided that Mr. Patel was eligible to receive an annual cash bonus of us to 15% of his annual base salary, upon the achievement of company-wide financial performance targets and personal performance goals as set by our Chief Executive Officer and the Executive Chairman of the Board. Mr. Patel received a $6,375 annual cash bonus during 2014. The employment agreement also provided that Mr. Patel was eligible to receive equity compensation under our equity compensation plans, including, without limitation, a grant, on the effective date of the employment agreement, of options to purchase 10,000 shares of our common stock, with full vesting after three years. In addition, under the employment agreement, we were required to reimburse Mr. Patel for business expenses incurred by him in accordance with our policies and procedures for expense reimbursement. Upon the termination of the employment agreement, Mr. Patel was entitled to receive all base salary compensation which was fully earned but had not yet been paid to him, and all of Mr. Patel's unvested equity based awards were forfeited. The employment agreement also includes non-solicitation, anti-raiding, non-disparagement and non-disclosure covenants by Mr. Patel.

Compensation of Directors

The Compensation Committee recommends director compensation to the Board of Directors, and the Board of Directors 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 of Directors, Audit Committee and Compensation Committee, on May 20, 2014, (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 of Directors, 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 the 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 10,000 shares of our Common Stock under our 2009 Equity Incentive Plan with an exercise price of $1.76 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 to the Board of Directors, on September 1, 2010, Suresh Vazirani and Kishore "Kris" Dudani, stated that, as then-employees of ERBA Mannheim, they would not require any compensation for their service on the Board of Directors, Audit Committee or Compensation Committee during such employment by ERBA Mannheim. 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 and, previously, Kishore "Kris" Dudani), will not receive any compensation for their service on the Board of Directors, Audit Committee or Compensation Committee.

Director Compensation – 2014

The following table sets forth certain information regarding the compensation paid to our directors for their service during the fiscal year ended December 31, 2014.

Name	Fees Earned or Paid in Cash	Stock Awards	Option Awards[2]	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	-	$ 15,700	-	-	-	$ 48,200
Gerald E. Gallwas	$ 20,000	-	$ 15,700	-	-	-	$ 35,700
David M. Templeton	$ 32,500	-	$ 15,700	-	-	-	$ 48,200
Sanjiv Suri [1]	-	-	-	-	-	-	-
John B. Harley, M.D., Ph.D.[1]	$ 10,000	-	-	-	-	-	$ 10,000

(1) At our Annual Meeting of Stockholders held on May 20, 2014, each of Dr. Harley and Mr. Suri did not stand for re-election to the Board of Directors. Accordingly, each of Dr. Harley’s and Mr. Suri’s term of service as a director expired at our 2014 Annual Meeting of Stockholders.

(2) Represents the aggregate grant date fair value of option awards calculated in accordance with Codification Topic 718, *Compensation – Stock Compensation.* Assumptions used in the calculation of these amounts are included in Note 10 to our Consolidated Financial Statements, *Shareholders’ Equity*, The table below sets forth, as of December 31, 2014, 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.	99,041
Gerald E. Gallwas	-
David M. Templeton	99,041
Sanjiv Suri	-
John B. Harley, M.D., Ph.D.	40,000

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 May 8, 2015, 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 May 8, 2015 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	88.1%
Transasia Bio-medicals Ltd.[2] Transasia House 8 Chandivali Studio Road Mumbai, India 400072	60,034,713	88.1%
Suresh Vazirani[2] Transasia House 8 Chandivali Studio Road Mumbai, India 400072	60,034,713	88.1%
Kishore “Kris” Dudani[2] Transasia House 8 Chandivali Studio Road Mumbai, India 400072	60,034,713	88.1%
Philippe Gadal, Pharm.D.	99,041(6)	*
Gerald E. Gallwas	77,788	*
Mohan Gopalkrishnan	30,000(7)	*
Ernesina Scala [3]	-	-
Prakash Patel[4]	-	-
Sanjiv Suri[5]	-	-
David M. Templeton	99,041(8)	*
All directors and executive officers as of May 8, 2015 as a group (7 persons)	60,340,583	88.1%

* 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 above) 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 Mannheim, Transasia and Messrs. Vazirani and Dudani may be deemed to have an aggregate beneficial ownership of 60,034,713, or 88.1%, of the issued and outstanding shares of our Common Stock; provided, however, that each of Messrs. Vazirani 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) Ms. Scala was appointed as our Chief Financial Officer on May 1, 2015.

(4) Mr. Patel served as our Controller until April 30, 2015, the effective date of his resignation.

(5) Mr. Suri resigned effective as of June 1, 2014. Prior to his resignation, Mr. Suri served as our Interim Chief Executive Officer from August 1, 2013 until June 1, 2014.

(6) Includes options to purchase 99,041 shares of our Common Stock granted to Dr. Gadal.

(7) Includes options to purchase 25,000 shares of our Common Stock granted to Mr. Mohan.

(8) Includes options to purchase 99,041 shares of our Common Stock granted to Mr. Templeton.

Equity Compensation Plan Information

The following table sets forth information, as of December 31, 2014, 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	808,082	$1.59	3,290,318
Equity compensation plans not approved by stockholders	0	$-	0
Total	808,082	$1.59	3,290,318

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

Certain Relationships and Related Transactions

During the years ended December 31, 2014 and 2013, we sold products to Transasia, and a subsidiary of ERBA Mannheim, for a total amount of approximately $2,375,000 and approximately $606,000 respectively.

During the year ended December 31, 2014, we began to incur management fees from ERBA Mannheim related to the management of global trade conferences and distributors in European, North African and Asian countries. During the year ended December 31, 2014, we incurred approximately $285,000 in such management fees to ERBA Mannheim.

During 2011, Delta Biologicals entered into a contract research and development agreement with ERBA Mannheim, as amended. Delta Biologicals incurred expenses related to the research and development mentioned above which were billed to ERBA Mannheim for reimbursement. For the years ended December 31, 2014 and 2013, contract research and development revenue under the agreement approximated Euro 436,000 (equivalent to approximately $576,000) and Euro 675,000 (equivalent to approximately $896,000), respectively.

We had net accounts receivable from ERBA Mannheim, Transasia and related subsidiaries of $1,489,000 and $1,835,000 as of December 31, 2014 and 2013, respectively, related to the above transactions and receivables from the sale of products and the reimbursement of various expenditures incurred on behalf of ERBA Mannheim.

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 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.

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) plus additional material costs, in seven monthly installments of Euro 50,000 from December 2012 through June 2013, for certain research and development endeavors. On July 24, 2013, JAS Diagnostics and Erba Diagnostics France mutually terminated the agreement above and Erba Diagnostics France agreed to refund to JAS Diagnostics all amounts paid under the agreement within 90 days. We continued to pay for the research and development costs through October 2013. We incurred total research and development costs of approximately $913,000, all of which were reimbursed by Erba Diagnostics France during the year ended December 31, 2013. The reimbursed research and development costs were recognized as a reduction to research and development expense included in the 2013 consolidated statement of operations.

Common Stock and Equity Transactions

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 66-2/3% of the issued and outstanding shares of our 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 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 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, 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 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, 2014 and 2013. As of December 31, 2014 and 2013, 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 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, 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. We used all of the proceeds of the Second Closing to consummate the acquisition of Drew Scientific.

Other Transactions

During the year ended December 31, 2013, ImmunoVision paid $10,000 to John B. Harley, M.D., Ph.D., who at the time was a member of the Company's Board of Directors, under that certain oral consulting agreement between Dr. Harley, and ImmunoVision pursuant to which Dr. Harley was paid $2,000 per month in consideration for his provision of technical guidance and business assistance to the subsidiary on an as-needed basis. The oral consulting agreement ended in May 2013.

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 years ended December 31, 2014 and 2013, the Company paid $10,000 under such royalty 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.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The following table sets forth the aggregate fees billed to us by Mayer Hoffman McCann P.C., or MHM, our principal accountant, for the fiscal years ended December 31, 2014 and 2013.

	For the years ended December 31,	
	2014	**2013**
Audit Fees	$ 226,000	$ 171,388
Audit-Related Fees	-	3,000
Tax Fees	-	-
All Other Fees	-	-
Total Fees	$ 226,000	$ 174,388

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” for 2013 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.

MHM has advised us that MHM leases substantially all of its personnel, who work under the control of MHM’s shareholders, from wholly-owned subsidiaries of CBIZ, Inc., in an alternative practice structure. Accordingly, substantially all of the hours expended on MHM’s engagement to audit our financial statements for the years ended December 31, 2014 and 2013 were attributed to work performed by persons other than MHM’s full-time, permanent employees.

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.

Exhibit Number	Description	Method of Filing
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	Certificate of Amendment to the Amended and Restated Certificate of Incorporation	Incorporated by reference to Appendix A of our Schedule 14A filed on August 22, 2013.
3.5	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.
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 25, 2015, by and between ERBA Diagnostics, Inc. and Citibank, N.A.	Incorporated by reference to our Form 8-K filed on March 30, 2015.
10.8	Form of Promissory Note, executed on March 25, 2015, made by ERBA Diagnostics, Inc. in favor of Citibank, N.A.	Incorporated by reference to our Form 8-K filed on March 30, 2015
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 Security Agreement, dated as of March 25, 2015, made by JAS Diagnostics, Inc., in favor of Citibank, N.A.	Incorporated by reference to our Form 8-K filed on March 30, 2015.

Exhibit Number	Description	Method of Filing
10.11	Form of Commercial Pledge Agreement, dated as of March 25, 2015, made by ERBA Diagnostics, Inc., in favor of Citibank, N.A.	Incorporated by reference to our Form 8-K filed on March 30, 2015.
10.12	Form of Commercial Guaranty Agreement, dated as of March 25, 2015, made by each of Diamedix Corporation, ImmunoVision, Inc., Drew Scientific, Inc., and JAS Diagnostics, Inc., in favor of Citibank, N.A.	Incorporated by reference to our Form 8-K filed on March 30, 2015.
10.13	Purchase and Sale Agreement, dated as of March 25, 2015, by and between Diamedix Corporation and Joe Management LLC	Incorporated by reference to our Form 8-K filed on March 26, 2015.
10.14	First Amendment to Agreement for Purchase and Sale of Real Property, dated as of May 8, 2015, by and between Diamedix Corporation and Joe Management LLC	Incorporated by reference to our Form 8-K filed on May 13, 2015.
10.15	1999 Performance Equity Plan	Incorporated by reference to our Form SB-2 filed on October 6, 1999.
10.16	2009 Equity Incentive Plan	Incorporated by reference to our Schedule 14A filed on May 8, 2009.
10.17	Form of Nonqualified Stock Option Agreement (Employee)	Incorporated by reference to our Form 8-K filed on June 16, 2009.
10.18	Form of Nonqualified Stock Option Agreement (Independent Director)	Incorporated by reference to our Form 10-K filed on March 30, 2011.
10.19*	Employment Agreement, dated May 31, 2014, by and between ERBA Diagnostics, Inc., and Mohan Gopalkrishnan	Incorporated by reference to our Form 8-K filed on June 4, 2014.
10.20*	Employment Agreement, dated June 6, 2014, by and between ERBA Diagnostics, Inc., and Prakash Patel	Incorporated by reference to our Form 8-K filed on June 10, 2014.
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.
31.1	Certification of Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith.
31.2	Certification of Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith.
32.1	Certification of Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	**
32.2	Certification of Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	**
101.INS	XBRL Instance Document	Filed herewith.
101. SCH	XBRL Taxonomy Extension Schema Document	Filed herewith.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document	Filed herewith.

Exhibit Number	Description	Method of Filing
101.LAB	XBRL Taxonomy Extension Labels Linkbase Document	Filed herewith.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document	Filed herewith.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document	Filed herewith.

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

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

SIGNATURES

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

ERBA DIAGNOSTICS, INC.

Dated: May 15, 2015

By: /s/ Mohan Gopalkrishnan
Mohan Gopalkrishnan,
Chief Executive Officer

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	May 15, 2015
/s/Mohan Gopalkrishnan Mohan Gopalkrishnan	Chief Executive Officer (Principal Executive Officer) (Principal Financial Officer) (Principal Accounting Officer)	May 15, 2015
/s/Kishore Dudani Kishore Dudani	Director	May 15, 2015
/s/Philippe Gadal, Pharm.D. Philippe Gadal, Pharm.D.	Director	May 15, 2015
/s/Gerald E. Gallwas Gerald E. Gallwas	Director	May 15, 2015
/s/David M. Templeton David M. Templeton	Director	May 15, 2015

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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