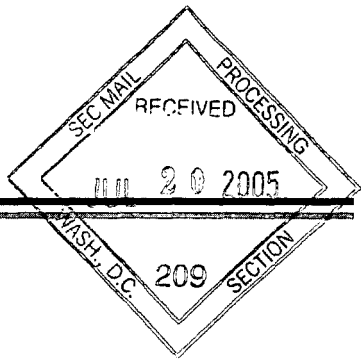
IVAX Diagnostics, Inc.

P.E. 12-31-04

2004 Annual Report

IVAX Diagnostics, Inc.



June 14, 2005

To Our Stockholders

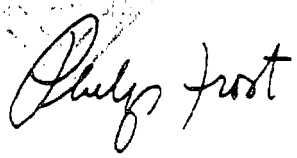
2004 was an important year in the development of IVAX Diagnostics, Inc. and we are pleased to provide you with a summary of the financial highlights and important events.

A major milestone for IVAX Diagnostics in 2004 was achieving profitability for the full year. The trend continued in the first quarter of 2005, with record revenues and income. For the full year 2004, revenues increased 7% to $18,933,000 from $17,673,000 in 2003. During this same period, income was $152,000 compared to a loss of $675,000 for 2003, an improvement of $827,000. Profit margins benefited from increased production volumes and manufacturing efficiencies. We are implementing additional manufacturing automation initiatives which will further improve production efficiency. Our installed base of instrumentation at customer sites continued to expand in 2004 which should drive sales of our reagent kits.

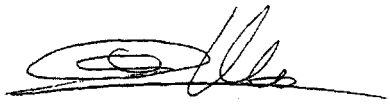
We placed the first PARSEC™ System, our new proprietary automated testing system, for evaluation testing at a customer site in Europe during the first quarter of 2005 and expect to receive final approval in Europe in the near future, followed by our European product launch. In the United States, we expect to begin placements later this year. We expect the PARSEC™ System to allow us to expand our market presence, particularly in markets and test sectors in which we do not currently compete. The hepatitis market is one of these markets and we are currently receiving the transfer to IVAX Diagnostics of previously announced hepatitis technology that will permit us to manufacture a full panel of hepatitis assays. We plan to add these important assays to the menu offered with our PARSEC™ System.

For our Mago® Plus automation program, we are expanding the testing capability of this system by incorporating immunofluorescence (IFA) testing. This would allow Mago® Plus users to simultaneously perform both ELISA and IFA testing and creates a more competitive analyzer to attract new customers. To enhance our distribution network, we have entered into agreements with a number of companies to sell IVAX Diagnostics' products in France, Germany, Austria, Hungary, Slovakia, and the Czech Republic. As our business model progresses, we expect our financial results to continue to improve.

We are enthusiastic about making IVAX Diagnostics an important company and hope that we can continue to serve our customers, employees, and stockholders well.



Phillip Frost, M.D.
Chairman of the Board of Directors



Giorgio D'Urso
President and Chief Executive Officer

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

FORM 10-K

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

For the fiscal year ended December 31, 2004
Commission File Number 1-14798

IVAX Diagnostics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**11-3500746**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

2140 North Miami Avenue, Miami, Florida 33127
(Address of principal executive offices, including zip code)

(305) 324-2300
(Registrant's telephone number, including area code)

Securities Registered Pursuant to Section 12(b) of the Act:

Common Stock, Par Value $0.01	**American Stock Exchange** **Boston Stock Exchange**
(Title of class)	**(Name of each exchange on which registered)**

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

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

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

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

The aggregate market value of the voting common stock held by non-affiliates of the registrant on June 30, 2004, was approximately $44,591,840.

As of March 18, 2005, there were 27,019,829 shares of common stock outstanding.

Documents Incorporated by Reference: None

IVAX Diagnostics, Inc.

Annual Report on Form 10-K
for the year ended December 31, 2004

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PART I

ITEM 1. BUSINESS

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. These statements are based on the beliefs and assumptions of our management and on the information currently available to it. Forward-looking statements may be preceded by, followed by, or otherwise include the words "may," "will," "believes," "expects," "anticipates," "intends," "plans," "estimates," "projects," "could," "would," "should," or similar expressions or statements that certain events or conditions may occur. Actual results, performance or achievements could differ materially from those contemplated, expressed or implied by these forward-looking statements. These forward-looking statements are based largely on our expectations and the beliefs and assumptions of our management and on the information currently available to it and are subject to a number of risks and uncertainties, including, but not limited to, the risks and uncertainties associated with: economic, competitive, political, governmental and other factors affecting us and our operations, markets and products; the success of technological, strategic and business initiatives, including our automation strategy and our development and commercial release of our new proprietary instrument system, named the PARSEC™ System; our ability to receive regulatory approval for the PARSEC™ System; the performance of the PARSEC™ System; the ability of the PARSEC™ System to be a factor in our growth; the ability of the PARSEC™ System to expand the menu of test kits we offer; making the PARSEC™ System our primary product; our ability to market the PARSEC™ System; our customers' integration of the PARSEC™ System into their operations; constantly changing, and our compliance with, governmental regulation, including "European Conformity" marking on our products sold throughout the European Union; our adoption or implementation of new accounting statements and pronouncements; our limited operating revenues and history of primarily operational losses; our ability to collect our accounts receivable and to make or change judgments and estimates regarding our allowances for doubtful accounts; our ability to utilize our deferred tax assets and to make or change judgments and estimates regarding our valuation allowances and reserves against our deferred tax assets; 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 internally manufacture our own hepatitis products and raw materials for these products, to obtain regulatory approval for these products and to become competitive in markets outside of the United States; our agreements with IVAX Corporation, or IVAX, third party distributors and key personnel; consolidation of our customers affecting our operations, markets and products; reimbursement policies of governmental and private third parties affecting our operations, markets and products; price constraints imposed by our customers and governmental and private third parties; our ability to consummate potential acquisitions of businesses or products; our ability to integrate acquired businesses or products; protecting our intellectual property; political and economic instability and foreign currency fluctuation affecting our foreign operations; the holding of substantially all of our cash and cash equivalents and marketable securities at a single brokerage firm, including risks relating to the bankruptcy or insolvency of such brokerage firm; litigation regarding products, distribution rights, intellectual property rights and product liability; voting control of our common stock by IVAX; conflicts of interest with IVAX and with our officers, directors and employees; and other factors discussed elsewhere in this Annual Report on Form 10-K. Many of these factors are beyond our control.

Business

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

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

Through these subsidiaries, we develop, manufacture, and market diagnostic test kits, or assays, and automated systems that are used to aid in the detection of disease markers primarily in the areas of autoimmune and infectious diseases. These tests, which are designed to aid in the identification of the causes of illness and disease, assist physicians in selecting appropriate patient treatment. Most of our tests are based on Enzyme Linked ImmunoSorbent Assay, or ELISA, technology, a clinical testing methodology used worldwide. Specific tests are prepared using a 96 well microplate format whereby specific antigens are typically coated on the wells of a microplate during the manufacturing process. A test using ELISA technology involves a series of reagent additions to the microplate causing a reaction that results in a visible color in the wells. The amount of color is directly proportionate to the amount of the specific analyte in the patient sample. Our kits are designed to be performed either manually or in an automated format. In addition to our line of diagnostic kits, we also design and manufacture laboratory instruments that perform the tests and provide fast and accurate results, while reducing labor costs. Our existing proprietary instruments, named the Mago® Plus and Aptus® systems, include a fully-automated ELISA processor operating with our own user-friendly software, allowing customers to perform tests in an automated mode. We have designed our new proprietary instrument system, named the PARSEC™ System, in a modular format, which we believe should permit different detection technologies to be incorporated. We expect that this design should enable customers to utilize not only ELISA-based kits, but also other methods such as chemiluminescent-based assays in the future. We also believe that the PARSEC™ System's design is scalable, which we believe should give customers the ability to "customize" the configuration of the PARSEC™ System to the testing and work flow requirements of their particular laboratories. We have not yet received regulatory approval for the PARSEC™ System, nor is it yet available for commercial release. We also develop, manufacture, and market raw materials, such as antigens used in the production of diagnostic kits.

Our management reviews financial information, allocates resources and manages the business as two segments defined by geographic region. One segment—the domestic region—contains our subsidiaries located in the United States and corporate operations. Our other segment—the Italian region—contains our subsidiary located in Italy. For additional information about our two segments, see Note 9 to our Consolidated Financial Statements.

Delta, which IVAX acquired in 1991, was established in 1980. From its facility located in Pomezia, Italy, it develops and manufactures scientific and laboratory instruments, including its proprietary Mago® Plus and Aptus® systems, which include hardware, reagents, and software. The Mago® Plus and Aptus® systems, in association with 104 specific assays acquired from Diamedix and third parties, as well as a complete line of allergy products, are sold directly in Italy through Delta's independent sales force and sales representatives, most of whom work exclusively for Delta. Delta also sells in Italy other diagnostic products manufactured by third parties. Approximately 90% of Delta's customers in Italy are government owned hospitals and the remaining 10% are private laboratories. Thus, sales in Italy are heavily concentrated in the public sector. Delta also serves as the distribution center for selling these same products to customers located in other European and international markets outside Italy. Some of these sales, such as in Spain and Portugal, are made through distributors while others are made on a direct basis. The sales made on a direct basis occur primarily in the United Kingdom, France and Germany. These sales are supported by our employees or sales agents based in England, France and Italy.

Diamedix was established in 1986 after it acquired all of the assets and retained substantially all of the personnel of Cordis Laboratories, Inc., a company that had developed, manufactured, and marketed diagnostic equipment since 1962. IVAX acquired Diamedix in 1987. Diamedix' products are sold in the United States through Diamedix' sales force. Diamedix manufactures 44 assays that the United States Food and Drug Administration, or FDA, has cleared and that are available to be run in conjunction with the Mago® Plus and Aptus® systems. These assays are sold under the trade name immunosimplicity®. Diamedix is located in Miami, Florida.

Since 1985, ImmunoVision has been developing, manufacturing, and marketing autoimmune reagents and research products for use by research laboratories and commercial diagnostic manufacturers. These

manufacturers (including Diamedix) use these antigens to produce autoimmune diagnostic kits. IVAX acquired ImmunoVision in 1995. ImmunoVision is located in Springdale, Arkansas.

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

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

Market. Our products are primarily associated with the in vitro diagnostics market. In vitro diagnostic assays are tests that are used to detect specific substances, usually either antigens or antibodies, outside the body. This usually involves using a blood sample or other bodily fluid sample for testing. The market for in vitro diagnostic products consists of reference laboratory and hospital laboratory testing, testing in physician offices, and over the counter testing, in which testing can be performed at home by the consumer. Industry analysts have estimated that the world market for in vitro diagnostics was $27.7 billion in 2003 and estimated to grow at a rate of 7% annually. Of this total $27.7 billion market, the world immunoassay market in which we operate is estimated by industry analysts to be $5.37 billion. We have focused our efforts on the niche market for autoimmune and infectious disease immunoassay products. Our ELISA autoimmune product line consists of 20 test kits that the FDA has cleared. These include test kits for screening antinuclear antibodies and specific tests to measure antibodies to dsDNA, SSA, SSB, Sm, Sm/RNP, Scl 70, Jo-1, Rheumatoid Factor, MPO, PR-3, TPO, TG, and others. These products are used for the diagnosis and monitoring of autoimmune diseases, including Systemic Lupus Erythematosus, or SLE, Rheumatoid Arthritis, Mixed Connective Tissue Disease, Sjogren's Syndrome, Scleroderma, and Dermatopolymyositis. Our infectious disease product line includes 24 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.

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

We are seeking to differentiate ourselves from our competitors through our proprietary instrument systems. While some of our competitors offer proprietary instruments, other competitors use third parties to manufacture these instruments for them. We believe that the cost advantage we enjoy from our own manufacture of the Mago® Plus and Aptus® systems and the PARSEC™ System, coupled with our production of certain autoimmune reagents at ImmunoVision and our production of diagnostic test kits at Diamedix, should position us to target new product markets for growth beyond the niche market for autoimmune and infectious disease immunoassay products in which we currently compete. We expect that our new proprietary PARSEC™ System should enable us to expand the menu of test kits that we currently offer and that we should be able to expand into testing sectors beyond the autoimmune and infectious disease products. We expect that the PARSEC™ System will be marketed to hospitals, reference testing laboratories, clinics and pharmaceutical, and biotechnology research companies. We presented the PARSEC™ System at the American Association for Clinical Chemistry (AACC) Clinical Lab Exposition in Los Angeles, California in July 2004 and the Medica Exhibition in Dusseldorf, Germany in November 2004. We have not yet received regulatory approval for the PARSEC™ System, nor is it yet available for commercial release.

Research and Development. We devote substantial resources for research and development. For the years ended December 31, 2004, 2003 and 2002, we spent $1.3 million, $1.3 million and $1.4 million, respectively, for research and development activities. There is no assurance that these expenditures will result in the development of new products or product enhancements, that we will successfully complete products currently 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.

Our research and development efforts are targeted primarily towards the development of our new proprietary PARSEC™ System. While there is no assurance that we will be successful, we are seeking to expand the test kits menu we offer in the autoimmune and infectious disease testing sectors and considering moving into additional diagnostic test sectors such as HIV, Hepatitis, and allergy detection. In September 2004, we signed a license agreement with an Italian diagnostics company that allows us access to its technology for manufacturing certain hepatitis products. This agreement is expected to enable us to become competitive in markets outside of the United States by providing us with the technology that, over time, would allows us to internally manufacture our own hepatitis products with the "CE Marking," as well as internally manufacture our own raw materials for these hepatitis products.

Sales and Marketing. We currently market our products in the United States through our own sales force to hospitals, reference laboratories, clinical laboratories, and research laboratories, as well as to other commercial companies that manufacture diagnostic products. We also sell some of our products to pharmaceutical and biotechnology companies. We market our products in certain international markets through a network of independent distributors. We market and sell our products in Italy through a network of salespersons and sales agents, most of whom work on an exclusive basis for Delta. We also sell our products in other global markets through a number of independent distributors. Sales personnel are trained to demonstrate our products in the laboratory setting. Our marketing and technical service departments located in Miami, Florida, Springdale, Arkansas, and Pomezia, Italy support their efforts. We participate in a number of industry trade shows in the United States and Europe.

The products we market 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.

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, our products are sold through tenders for multiple year periods. Due to the efforts exercised by many governments to contain healthcare costs, there has been a constant effort to consolidate laboratory units and, consequently, the bid process continues to become even more competitive.

On May 15, 2002, we consummated the acquisition of certain of the assets of the global enzyme immunoassay product line of Sigma Diagnostics for approximately $2,212,000 and the assumption of certain liabilities. As a result of the consummation of the transaction with Sigma Diagnostics, we no longer sell reagents or instrumentation to Sigma Diagnostics, which had been our largest customer during 2001 and 2000 and which had marketed such reagents and instrumentation throughout the world under previous agreements with us. Instead, we sell enzyme immunoassay instrumentation and reagents directly to Sigma Diagnostics' former

customer base. Selected employees previously affiliated with Sigma Diagnostics, primarily in the field sales, instrument service and technical support areas, joined us. As a result of the consummation of the transaction with Sigma Diagnostics, our previous agreements with Sigma Diagnostics have been terminated.

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

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

Competition. We compete on a worldwide basis and there are numerous competitors in the specific market sectors in which we offer our products. These competitors range from major pharmaceutical companies to development stage diagnostic companies. Many of these companies, such as Abbott Laboratories and Diagnostic Products Corporation, 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 autoimmune is very fragmented as it is comprised of primarily small companies with no single company possessing a dominant market position. We compete in the marketplace on the basis of the quality of our products, price, instrument design and efficiency, as well as our relationships with customers. In addition to Abbott Laboratories and Diagnostic Products Corporation, our competitors include Bio-Rad Laboratories, DiaSorin, Meridian Bioscience, Inc., Inverness Medical Innovations, Inc., Stratagene Corporation and Trinity Biotech plc.

The in vitro diagnostic market in which we sell many of our products is highly competitive. The market for our products is characterized by continual and rapid technological developments that have resulted in, and will likely continue to result in, substantial improvements in product function and performance. Our success will depend, in part, on our ability to anticipate changes in technology and industry requirements and to respond to technological developments on a timely basis either internally or through strategic alliances. Several companies have developed, or are developing, scientific instruments and assays that compete or will compete directly with products we market. Many existing and potential competitors have substantially greater financial, marketing, research, and technological resources, as well as established reputations for success in developing, manufacturing, selling, and servicing products, than us. Competitors that are more vertically integrated than us may have more flexibility to compete effectively on price. We expect that existing and new competitors will continue to introduce products or services that are, directly or indirectly, competitive with those that we sell. Such competitors may succeed in developing products that are more functional or less costly than those sold by us and may be more successful in marketing such products. These and other innovations in the rapidly changing medical technology market will 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 products or technologies obsolete.

Personnel. As of December 31, 2004, we had approximately 116 full time employees, of whom 17 were managerial, 47 were technical and manufacturing, 14 were administrative, and 38 were sales and marketing.

Intellectual Property. In December 1994, Diamedix entered into an intellectual property agreement with two inventors pursuant to which it acquired all rights, title, and interest in the Mago® instrument, including all related software and technical information. During 2003, Diamedix completed its obligation to make payments under the intellectual property agreement. Separately, in December 1994, the pre-merger Diagnostics entered into consulting agreements with each of the inventors. Only one of these consulting agreements, which was amended in July 2003, currently remains in effect.

The technology associated with the design and manufacture of the Mago® and Aptus® instruments is not protected by patent registrations or license restrictions. The Mago® instrument has been our primary product. In the future, we expect that the PARSEC™ System will become our primary product. We have filed several patent

applications related to the new innovative features in the PARSEC™ System. 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.

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

Governmental Regulation. The testing, manufacturing, and sale of our products are subject to regulation by numerous governmental authorities, principally the FDA. To comply with FDA requirements, we must, among other things, manufacture our products in conformance with the FDA's medical device Quality System regulations. Diamedix is listed as a registered establishment with the FDA and Delta has received UNI ISO 9001 certification complemented by the requirements of UNI CEI EN ISO 13485 validating its quality system. 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 may or may not be subject to pre-market notification. Pre-market notifications must be submitted to the FDA before products can be commercially distributed. Some Class I devices have been deemed exempt from this requirement by the FDA. Class II devices are subject to the same general controls, pre-market notification and performance standards. Usually, Class III devices are those that must receive pre-market approval by the FDA to ensure their safety and effectiveness. Most of our products are classified as Class I or II devices. Generally, before a new test kit can be introduced to the market, it is necessary to obtain FDA clearance in the form of a pre-market 510(k) notification. A 510(k) notification provides data to show that the new device is substantially equivalent to other devices in the marketplace. Almost all of the products sold by us have received 510(k) clearance. In addition, customers using diagnostic tests for clinical purposes in the United States are also 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.

Additionally, the products we sell are subject to extensive regulation by governmental authorities in the United States and other countries, including, among other things, the regulation of the testing, approval, manufacturing, 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 products may have received FDA clearance. In order to be commercially distributed throughout the European Union, certain of our products must bear the "CE Marking." All of the products that we currently sell throughout the European Union are in conformity with the applicable "CE" regulations under the In Vitro Diagnostics Directive. We have also received an ISO 13485:1996 certificate, giving us approval for Europe and Canada. 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.

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. There is no assurance that we will attain necessary approvals on a timely basis, if at all. 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. There can be no assurance that we will not encounter delays in obtaining necessary domestic or foreign regulatory approvals, if at all, or failures to comply with applicable regulatory requirements, or extensive changes in regulation.

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.

The evolving and complex nature of regulatory requirements, the broad authority and discretion of the FDA and the high level of regulatory oversight in our industry result in a continuing possibility that our business and results of operations may be adversely affected by regulatory issues despite our efforts to maintain compliance with regulatory requirements.

Available Information. Our Internet web site is www.ivaxdiagnostics.com. We make available, free of charge, through our web site, 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 pursuant to Section 13(d) 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. Information contained in our web site is not part of this Annual Report on Form 10-K and shall not be incorporated by reference herein.

ITEM 2. PROPERTIES

Our corporate headquarters are located in Miami, Florida. Our corporate headquarters share facilities with Diamedix, which owns approximately 56,000 square feet of buildings at its facility in Miami, Florida. From this facility, Diamedix conducts research and development of in vitro diagnostic products, reagent kit manufacturing, marketing, and corporate management activities. Delta leases approximately 27,000 feet of industrial space in Pomezia, Italy. This facility is where our proprietary instrumentation is manufactured. ImmunoVision leases approximately 5,700 square feet of commercial space in Springdale, Arkansas.

We believe our facilities are in satisfactory condition, are suitable for their intended use and, in the aggregate, have capacities in excess of those necessary to meet our present needs. A portion of our facilities, as well as our corporate headquarters and other critical business functions are located in areas subject to hurricane casualty risk. Although we have certain limited protection afforded by insurance, our business and our earnings could be materially adversely affected in the event of a major windstorm.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matters were submitted to a vote of security holders during the quarter ended December 31, 2004.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock is listed on the American Stock Exchange and trades under the symbol IVD.

As of the close of business on March 28, 2005, there were approximately 49 holders of record of our common stock.

The following table sets forth the high and low sales price of a share of our common stock for each quarter in 2004 and 2003, as reported by the American Stock Exchange:

	High	Low
2004		
Fourth Quarter	$5.52	$4.01
Third Quarter	6.45	5.17
Second Quarter	7.73	5.10
First Quarter	7.41	4.48
2003		
Fourth Quarter	$5.36	$3.93
Third Quarter	5.79	4.11
Second Quarter	5.15	1.92
First Quarter	2.26	1.35

We did not pay cash dividends on our common stock during 2004 or 2003 and we do not intend to pay any cash dividends in the foreseeable future.

ITEM 6. SELECTED FINANCIAL DATA

The following table sets forth selected historical financial data as of and for the fiscal years ended December 31, 2004, 2003, 2002, 2001 and 2000 that has been derived from, and is qualified by reference to, our Consolidated Financial Statements. The information set forth below should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operation" and the Consolidated Financial Statements and related Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K. The historical selected financial data prior to consummation of the merger are those of the pre-merger Diagnostics with retroactive restatement of equity and earnings per share.

	For the Years Ended December 31,				
	2004	2003	2002	2001	2000
	(In thousands except per share data)				
Consolidated Statement of Operations Data:					
Net revenue	$18,933	$17,673	$13,841	$10,299	$11,793
Income (loss) from operations[1]	$ (314)	$ (1,031)	$ (3,498)	$ (3,874)	$ 162
Net income (loss)[1]	$ 152	$ (675)	$ (2,830)	$ (3,509)	$ (1,855)
Net income (loss) per common share[1]	$ .01	$ (.02)	$ (.10)	$ (.13)	$ (.09)
Weighted average number of shares outstanding					
Basic	27,341	27,590	28,488	26,879	20,000
Diluted	28,543	27,590	28,488	26,879	20,000

	As of December 31,				
	2004	2003	2002	2001	2000
	(In thousands except per share data)				
Balance Sheet Data:					
Working capital	$22,993	$24,334	$23,521	$27,812	$ 6,029
Total assets	$36,914	$38,365	$37,423	$40,147	$19,113
Total liabilities	$ 4,868	$ 4,402	$ 4,027	$ 3,347	$11,894
Total stockholders' equity	$32,046	$33,963	$33,396	$36,800	$ 7,219

(1) As discussed in Note 2 to the Consolidated Financial Statements, in accordance with SFAS No. 142, we discontinued the amortization of goodwill effective January 1, 2002. The selected historical financial data for the years ended December 31, 2001 through December 31, 2000 has not been adjusted for the effect of this accounting change.

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

The following discussion and analysis should be read in conjunction with our Consolidated Financial Statements and the related Notes to Consolidated Financial Statements on pages 20 to 39 of this Annual Report on Form 10-K.

Overview

We are the parent corporation of the following three subsidiaries:

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

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

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

From its facility located in Pomezia, Italy, Delta develops and manufactures scientific and laboratory instruments, including its proprietary Mago® Plus and Aptus® systems, which include hardware, reagents, and software. The Mago® Plus and Aptus® systems, in association with 104 specific assays acquired from Diamedix and third parties, as well as a complete line of allergy products, are sold directly in Italy through Delta's independent sales representatives, most of whom work exclusively for Delta. Delta also sells in Italy other diagnostic products manufactured by third parties. Approximately 90% of Delta's customers in Italy are government owned hospitals and the remaining 10% are private laboratories. Thus, sales in Italy are heavily concentrated in the public sector.

Diamedix' products are sold in the United States through Diamedix' sales force. Diamedix markets 44 assays that the FDA has cleared and that are available to be run in conjunction with the Mago® Plus and Aptus® systems. These assays are sold under the trade name immunosimplicity®.

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

The historical financial statements prior to the merger of us and the pre-merger Diagnostics are those of the pre-merger Diagnostics with no adjustments except for retroactive restatement, as if a stock split occurred, to reflect the 20,000,000 shares of common stock that IVAX received in the merger as outstanding for all periods presented.

Results of Operations

Year Ended December 31, 2004 Compared to the Year Ended December 31, 2003

Overview

Net income in 2004 was $152,000 compared to a net loss in 2003 of $675,000. Contributing to this improvement was an increase in revenue of $1,260,000 which, excluding the effect of foreign currency fluctuations, was principally driven by an increase in revenue from reagents sold due to an increased number of instrument placements. The combination of this increased revenue and an improved gross profit as a percentage of net revenues caused our gross profits to increase to $11,209,000 in 2004 from $10,189,000 in 2003. Our operating expenses increased by $303,000, primarily as a result of an increase of $476,000 in selling expenses offset by a $209,000 decrease in general and administrative expenses. As a result, operating loss improved from a loss of $1,031,000 in 2003 to a loss of $314,000 in 2004.

Net Revenues and Gross Profit

	2004	2003	Period over Period Increase (Decrease)
Net Revenues Excluding Intercompany Sales			
Domestic	$12,112,000	$11,700,000	$ 412,000
Italian	6,821,000	5,973,000	848,000
Total	18,933,000	17,673,000	1,260,000
Cost of Sales	7,724,000	7,484,000	240,000
Gross Profit	$11,209,000	$10,189,000	$1,020,000
% of Total Net Revenues	59.2%	57.7%	

Net revenues in 2004 increased $1,260,000, or 7.1%, from 2003. This increase was comprised of increases in external net revenues of $848,000 from Italian operations and $412,000 from domestic operations. The increase in external net revenues from Italian operations of 14.2% was primarily attributable to an increase in revenue due to fluctuations of the United States dollar relative to the Euro, as further discussed in "Currency Fluctuations" below. As measured in Euros, Italian revenues increased primarily as a result of higher revenue generated from reagent sales due to an increased number of instrument placements, partially offset by decreased revenue resulting from a lower volume of instrument sales. Domestic external net revenues in 2004 increased by 3.5% from 2003. This increase was primarily due to greater revenue derived from reagent sales due to an increased number of instrument placements as well as revenue from a contract manufacturing arrangement which commenced in December 2003, and was partially offset by decreased revenue from a lower volume of instrumentation sales. Gross profit in 2004 increased $1,020,000, or 10%, from the prior year. The increases in gross profit and gross profit as a percentage of net revenues were primarily attributable to the increase in net revenues as well as manufacturing efficiencies gained from the replacement of products manufactured by others with products manufactured by us. Also contributing to the increase in gross profit was the effect of exchange rate fluctuations of the United States dollar relative to the Euro.

Operating Expenses

	2004	% of Revenue	2003	% of Revenue	Period over Period Increase (Decrease)
Selling Expenses					
Domestic	$ 3,529,000	18.6%	$ 3,470,000	19.6%	$ 59,000
Italian	2,283,000	12.1%	1,866,000	10.6%	417,000
Total	5,812,000	30.7%	5,336,000	30.2%	476,000
General and Administrative	4,379,000	23.1%	4,588,000	26.0%	(209,000)
Research and Development	1,333,000	7.0%	1,297,000	7.3%	36,000
Total Operating Expenses	$11,524,000	60.9%	$11,221,000	63.5%	$ 303,000

Selling expenses in 2004 increased by $476,000 from 2003. The increase of $417,000 in the Italian portion of selling expenses was primarily due to the effect of exchange rate fluctuations and, when measured in local currency, increased payroll costs. Promotional costs related to our anticipated new PARSEC™ instrument system also contributed to the increase. Domestic selling expenses increased $59,000, also primarily as a result of increased payroll costs, but were partially offset by decreased promotional costs. General and administrative expenses decreased $209,000 from 2003 partially due to a decrease in compensation expense that includes the result of the completion on June 30, 2003 of the amortization of noncash stock option compensation costs recorded as a result of the merger between b2bstores.com and the pre-merger Diagnostics. General and administrative expenses were also lower in 2004 than in 2003 due to reduced legal costs, but higher insurance expenses partially offset these decreases. Research and development expenses increased $36,000 due to an increase in Italian research and development expenses to $539,000 in 2004 from $472,000 in 2003, partially offset by a decrease in domestic research and development expenses to $794,000 in 2004 from $824,000 in 2003. The increase in research and development expenses was primarily the result of increased Italian research and development expenses due to the effect of exchange rate fluctuations, partially offset by lower payroll and supply costs. The future level of research and development expenditures will depend on, among other things, the outcome of ongoing testing of products and instrumentation under development, delays or changes in government required testing and approval procedures, technological and competitive developments, strategic marketing decisions and liquidity.

Loss from Operations

Losses from operations were $314,000 and $1,031,000 in 2004 and 2003, respectively. Excluding intersegment elimination adjustments, which decreased consolidated loss from operations by $137,000, the loss from operations in 2004 was composed of losses from operations of $224,000 from domestic operations and $227,000 from Italian operations. Excluding intersegment elimination adjustments, which increased consolidated loss from operations by $10,000, the loss from operations in 2003 was composed of a loss from operations of $944,000 from domestic operations and $77,000 from Italian operations.

Other Income, Net

Interest income decreased to $223,000 in 2004 from $226,000 in 2003. Other income, net totaled $225,000 during 2004, compared to $211,000 in 2003. Amounts included in other income, net in 2004 and 2003 were primarily net foreign currency gains by our Italian subsidiary on transactions which were denominated in currencies other than its functional currency.

Income Tax Provision

During 2004 we recorded an income tax benefit of $19,000 compared to a tax provision of $80,000 in 2003. The benefit was realized by our Italian operation as a result of before tax losses in Italy. The 2003 tax provision relates primarily to Italian local income taxes based upon applicable statutory rates effective in Italy.

Net Income (Loss)

We generated net income in 2004 of $152,000 compared to a net loss of $675,000 in 2003. Our net income per basic and diluted common share was $0.01 in 2004 compared to basic and diluted net loss per common share of $0.02 in 2003. The net income in 2004 and the net loss in 2003 resulted primarily from the various factors discussed above. See Note 2, Summary of Significant Accounting Policies, in the Notes to Consolidated Financial Statements included elsewhere in this report on Form 10-K, for the calculation of earnings per share.

Year Ended December 31, 2003 Compared to the Year Ended December 31, 2002

Overview

Revenue growth in 2003 was principally driven by revenue attributable to our sale of reagents to customers we obtained as a result of our May 2002 transaction with Sigma Diagnostics. The combination of this increased volume of sales of reagents and the conversion of customers we obtained as a result of our transaction with Sigma Diagnostics from reagent kits formerly sold by Sigma Diagnostics that were obtained from third-party manufacturers to reagent kits manufactured by us allowed us to increase our gross profit as a percentage of net revenues to 57.7% in 2003 from 47.5% in 2002. Our operating expenses increased by $1,146,000, including an increase of $699,000 in selling expenses and an increase in general and administrative expenses of $577,000. Despite these increased expenses, operating results improved from a loss of $3,498,000 in 2002 to a loss of $1,031,000 in 2003.

Net Revenues and Gross Profit

	2003	2002	Period over Period Increase (Decrease)
Net Revenues Excluding Intercompany Sales			
Domestic	$11,700,000	$ 9,000,000	$2,700,000
Italian	5,973,000	4,841,000	1,132,000
Total	17,673,000	13,841,000	3,832,000
Cost of Sales	7,484,000	7,265,000	219,000
Gross Profit	$10,189,000	$ 6,576,000	$3,613,000
% of Total Net Revenues	57.7%	47.5%	

Net revenues increased $3,832,000, or 27.7%, in 2003 compared to 2002. This increase was comprised of an increase of $2,700,000 in external net revenues from domestic operations and an increase of $1,132,000 in external net revenues from Italian operations. Revenue from domestic operations increased 30.0% primarily due to revenue from reagents sold to customers obtained as a result of our transaction with Sigma Diagnostics as well as volume increases in reagent revenue generated from new instrumentation placements. The increase in external net revenues from Italian operations of 23.4% was primarily attributable to an increase in revenue due to fluctuations of the United States dollar relative to the Euro, as further discussed in "Currency Fluctuations" below. As measured in Euros, the increase in Italian revenue was primarily due to increased reagent sales outside of Italy to customers obtained as a result of our transaction with Sigma Diagnostics as well as increased international sales efforts. Gross profit in 2003 increased $3,613,000, or 54.9%, from the prior year. The increase in gross profit and gross profit as a percentage of total net revenues was primarily attributable to increased domestic revenue, the conversion of former Sigma Diagnostics customers to reagent kits manufactured by us rather than versions of reagent kits formerly sold by Sigma Diagnostics that were obtained from third-party manufacturers, and the manufacturing efficiencies we achieved that were generated by the resulting increases in the volume of our reagent kits.

Operating Expenses

	2003	% of Revenue	2002	% of Revenue	Period over Period Increase (Decrease)
Selling Expenses					
Domestic	$ 3,470,000	19.6%	$ 3,141,000	22.7%	$ 329,000
Italian	1,866,000	10.6%	1,496,000	10.8%	370,000
Total	5,336,000	30.2%	4,637,000	33.5%	699,000
General and Administrative	4,588,000	26.0%	4,011,000	29.0%	577,000
Research and Development	1,297,000	7.3%	1,427,000	10.3%	(130,000)
Total Operating Expenses	$11,221,000	63.5%	$10,075,000	72.8%	$1,146,000

Selling expenses in 2003 increased $699,000 compared to 2002. The increase in the domestic portion of selling expenses of $329,000 was primarily due to greater domestic payroll costs related to the increase in sales personnel obtained as a result of our transaction with Sigma Diagnostics as well as increased domestic sales efforts. The $370,000 increase in expenses incurred in Italy in 2003 compared to expenses incurred in Italy in 2002 was primarily due to the effect of exchange rate fluctuations. General and administrative expenses increased $577,000 from 2002, primarily due to increased insurance and legal costs as well as expenses related to the integration of the certain assets acquired from Sigma Diagnostics. Partially offsetting this increase was a decrease in compensation expense due to the completion on June 30, 2003 of the amortization of noncash stock option compensation costs recorded as a result of the merger between b2bstores.com and the pre-merger Diagnostics. Research and development expenses decreased $130,000 from research and development expenses recorded in 2002, primarily as a result of a decrease in domestic research and development expenses to $825,000 in 2003 from $953,000 in 2002. This decrease was primarily due to reductions in labor and supply and consumables costs. Additionally, Italian research and development expenses decreased to $472,000 in 2003 from $473,000 in 2002. Exclusive of the effect of exchange rate fluctuations, Italian research and development expenses decreased due to reduced instrumentation development costs, primarily as a result of a reduction in consulting expenses. The future level of research and development expenditures will depend on, among other things, the outcome of ongoing testing of products and instrumentation under development, delays or changes in government required testing and approval procedures, technological and competitive developments, strategic marketing decisions and liquidity.

Operating Loss

Operating losses were $1,031,000 and $3,498,000 during 2003 and 2002, respectively. Exclusive of intersegment elimination adjustments, which increased the consolidated operating loss by $10,000, our operating loss in 2003 was composed of an operating loss of $944,000 from domestic operations and an operating loss of $77,000 from Italian operations. Excluding intersegment elimination adjustments, which increased consolidated operating loss by $21,000 in 2002, domestic operations incurred an operating loss of $3,142,000 and Italian operations generated an operating loss of $335,000.

Other Income

Interest income decreased to $226,000 in 2003 from $465,000 in 2002. The decrease of $239,000 was primarily due to lower interest rates in 2003 as well as a reduction in cash and cash equivalents and marketable securities. Other income, net, totaled $211,000 during 2003 compared to $77,000 in 2002, an increase of $134,000. This increase was due to larger net foreign currency gains recognized in 2003 by our Italian subsidiary on transactions which were denominated in currencies other than its functional currency.

Liquidity and Capital Resources

At December 31, 2004, our working capital was $22,993,000 compared to $24,334,000 at December 31, 2003 and $23,521,000 at December 31, 2002. Cash and cash equivalents totaled $7,493,000 at December 31,

2004, $2,865,000 at December 31, 2003 and $15,942,000 at December 31, 2002. Short-term marketable securities were $4,650,000 at December 31, 2004 and $12,600,000 at December 31, 2003. Certain reclassifications of cash and cash equivalents and short-term marketable securities have been made to prior year consolidated financial statements to conform to the current year presentation. In the consolidated balance sheets, we reclassified from cash and cash equivalents to marketable securities $12,600,000 and $20,950,000 as of December 31, 2003 and 2001 (no reclassification was required as of December 31, 2002), respectively, which resulted in reclassifications to the consolidated statements of cash flows for the years ended December 31, 2003 and 2002. Our short-term marketable securities are investments in auction rate debt securities with final maturities longer than one year, but with interest rates typically resetting every 28 or 35 days through an auction mechanism. These short-term marketable securities consist primarily of taxable municipal bonds and government agency securities. Substantially all of our cash and cash equivalents and short-term marketable securities are presently held at one national 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 only invest in select money market instruments, municipal securities and corporate issuers.

Net cash of $22,000 was provided by operating activities during 2004, compared to $530,000 that was provided by operating activities in 2003 and $2,251,000 that was used in 2002. Cash provided by operating activities during 2004 was primarily the result of cash generated from operating results, adjusted for non-cash items, of $1,256,000 and an increase of $115,000 in long-term liabilities primarily as a result of reduced payments for required severance and retirement costs in Italy, offset by a net working capital increase, excluding the change in cash balance, of $1,355,000. This increase in net working capital was principally due to increases in accounts receivable and inventories, particularly components necessary for the future production of the PARSEC™ System, as well as an increase in other current assets. Cash provided in 2003 was principally the result of cash provided by operating results, adjusted for non-cash items, of $959,000 that were partially offset by an increase in net working capital, excluding the change in cash, of $460,000. This increase in net working capital was primarily the result of an increase in accounts receivable and other current assets. During 2002 cash was used in operating activities primarily as the result of an operating loss, adjusted for non-cash items, of $1,331,000 and an increase in net working capital, excluding the change in cash balance, of $717,000. The net working capital increase was caused principally by an increase in accounts receivable, which includes the effect of sales made to customers obtained as a result of our transaction with Sigma Diagnostics, and was partially offset by reductions in inventories and other current assets.

Net cash of $7,218,000 was provided by investing activities during 2004, compared to $13,698,000 that was used during 2003 and $17,513,000 that was provided during 2002. The increase in cash provided by investing activities in 2004 compared to 2003 and the use of cash from investing activities in 2003 compared to 2002 was primarily the result of the net sale or purchase of marketable securities in each of the respective years. A reduction in our acquisitions of equipment on lease, including a reduction in the cost of those instruments, also contributed to the increase in cash provided from investing activities in 2004 compared to 2003. The use of approximately $2,212,000 for our acquisition of certain assets of the enzyme immunoassay product line of Sigma Diagnostics in May 2002 contributed to the decrease in cash used for investing activities during 2003 compared to 2002.

Net cash of $2,579,000 was used in financing activities in 2004 compared to $266,000 that was provided by financing activities during 2003 and $1,959,000 that was used in financing activities in 2002. The increase in cash utilized in 2004 compared to 2003 was due to our June 25, 2004 use of approximately $2,629,000 to purchase and redeem 657,125 shares of our common stock from a group of three unaffiliated stockholders at an exercise price of $4.00 per share in accordance with the terms of a previously announced Redemption Agreement. These shares have been retired and have resumed the status of authorized and unissued shares. The increase in cash provided during 2003 compared to 2002 was due to our repurchase of approximately $2,054,000 worth of common stock in 2002 as part of our share repurchase program, which includes approximately $1,655,800 that we used to repurchase shares of our common stock under the terms of a previously announced

Redemption Agreement. We made no repurchases of our common stock during 2004 or 2003 as part of the common stock repurchase program approved by our Board of Directors in May 2002.

Our product research and development expenditures are expected to be approximately $2,000,000 during 2005. Actual expenditures will depend upon, among other things, the outcome of clinical testing of products under development, delays or changes in government required testing and approval procedures, technological and competitive developments, strategic marketing decisions and liquidity. There can be no assurance that these expenditures will result in the development of new products or product enhancements, that we will successfully complete products under development, that we will obtain regulatory approval or that any approved product will be produced in commercial quantities, at reasonable costs, and be successfully marketed. In addition, we estimate that cash of approximately $1,100,000 will be required in fiscal 2005 to improve and expand our facilities, equipment and information systems. Included in these improvements are anticipated purchases of equipment that will be necessary to integrate the acquisition of technology expected to be received by us under our license agreement with an Italian diagnostics company. Additionally, if certain performance objectives are satisfied regarding the transfer of this technology to our facility in Italy, then we will be required to pay a total of approximately $1,300,000 in milestone payments under the license agreement.

Our principal source of short term liquidity is existing cash and cash equivalents and marketable securities received as a result of cash received from the completion of the merger between b2bstores.com and the pre-merger Diagnostics, which we believe will be sufficient to meet our operating needs and anticipated capital expenditures over at least the next twelve months. For the long term, we intend to utilize principally existing cash and cash equivalents and marketable securities, as well as internally generated funds, which are anticipated to be derived primarily from the sale of existing diagnostic and instrumentation products and diagnostic and instrumentation products currently under development. To the extent that these sources of liquidity are insufficient, we may consider issuing debt or equity securities or curtailing or reducing our operations.

We maintain allowances for doubtful accounts, particularly in Italy for the operations of our Italian subsidiary, for estimated losses resulting from the inability of our customers to make required or timely payments. Payment cycles are longer in Italy than in the United States. If we require additional allowances, our operating results could be materially adversely affected during the period in which the determination to increase the allowance is or was made. We have reached an agreement with certain customers within a region of Italy which is expected to result in receipt of a payment of approximately $2 million Euro, much of which is delinquent, later in 2005. While we expect payment in 2005, payment cannot be assured and allowances related to such receivables will not be reversed until such amounts are received.

On May 15, 2002, we consummated our acquisition of certain of the assets of the global enzyme immunoassay product line of Sigma Diagnostics for $2,211,747 and the assumption of certain liabilities. The fair value of assets acquired of $2,456,747 includes reagent and instrumentation inventory as well as enzyme immunoassay instrumentation placed at customer locations. Selected employees previously affiliated with Sigma Diagnostics, primarily in the field sales, instrument service and technical support areas, joined us. As a result of the consummation of the transaction with Sigma Diagnostics, our previous agreements with Sigma Diagnostics have been terminated.

Contractual Obligations. The following table summarizes our significant contractual obligations as of December 31, 2004, and the effect such obligations are expected to have on our liquidity and cash flows in future periods.

		Payments due by period			
	Total	Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
Operating lease obligations	$ 741,000	$475,000	$266,000	$ —	$ —
Unconditional purchase obligations	24,000	15,000	9,000	—	—
Other long-term obligations	616,000	—	62,000	61,000	493,000
Total contractual cash obligations	$1,381,000	$490,000	$337,000	$61,000	$493,000

The expected timing of payment of the obligations described in the table above is estimated based on current information. Timing of payments and actual amounts paid may be different depending on a number of factors.

Off-Balance Sheet Arrangements. As of December 31, 2004, we had no off-balance sheet arrangements that are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material.

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. 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, income and other tax accruals, warranty obligations, and contingencies and litigation. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our assumptions and estimates may, however, prove to have been incorrect and our actual results may differ from these estimates under different assumptions or conditions. We believe the following critical accounting policies and the judgments and estimates we make concerning their application have significant impact on our consolidated financial statements.

A principal source of revenue is 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. In exchange, we include a Mago® Plus instrument and any required instrument service, which are paid for by the customer through these reagent kit purchases over the life of the commitment. We recognize revenue from the reagent kit sales when title passes, which is generally at the time of shipment. Should actual reagent kit or instrument failure rates significantly increase, our future operating results could be negatively impacted by increased warranty obligations and service delivery costs.

We maintain allowances for doubtful accounts, particularly in Italy for the operations of our Italian subsidiary, for estimated losses resulting from the inability of our customers to make required payments. In many instances our receivables in Italy, while currently due and payable, take in excess of a year to collect. If the financial condition of our customers were 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 during the period in which the determination or allowance is or was made. Our allowances for doubtful accounts were $3,081,000 and $2,898,000 at December 31, 2004 and 2003, respectively. A provision for losses on accounts receivable of $20,000 was recorded in 2004, while $141,000 was recorded in 2003.

We regularly review inventory quantities on hand, including components for current and future versions of instrumentation, and, if necessary, record a provision for excess and obsolete inventory based primarily on our estimates of product demand and production requirements. These estimates of future instrumentation and diagnostic kit product demand may prove to be inaccurate, in which case any resulting adjustments to the value of inventory would be recognized in our cost of goods sold at the time of such determination. Inventory reserves were $436,000 and $936,000 as of December 31, 2004 and 2003, respectively. During 2004, $143,000 was charged to cost and expenses while $291,000 was charged in 2003. Included within our inventory balance at December 31, 2004 was approximately $800,000 in PARSEC™ instrumentation and instrument components.

Pursuant to SFAS No. 142, *Goodwill and Other Intangible Assets,* we analyzed our goodwill for impairment issues and will continue to do so in future periods. In assessing the recoverability of our goodwill and other

intangibles, we made assumptions regarding estimated future cash flows, including current and projected levels of income, business trends, prospects and market conditions, to determine the fair value of the respected assets. If these estimates or their related assumptions change in the future, we may be required to record impairment charges for these assets not previously recorded. Any resulting impairment loss would be recorded as a charge against our earnings and could have a material adverse impact of our financial condition and results of operations.

We accounted for income taxes on our consolidated financial statements on a stand-alone basis as if we had filed our own income tax returns. However, the pre-merger Diagnostics reported its income taxes until the merger with b2bstores.com as part of a consolidated group. Therefore, all domestic net operating losses generated prior to the merger were utilized by IVAX. Since the merger, we have experienced net domestic losses from operations. Accounting principles generally accepted in the United States require that we record a valuation allowance against the deferred tax asset associated with these losses if it is "more likely than not" that we will not be able to utilize the net operating loss to offset future taxes. Due to the cumulative net losses from the operations of our domestic operations since the merger, we have provided full valuation reserves of $3,146,000 against domestic deferred tax assets and currently provide for only foreign income taxes because we believe we have sufficient prior years' net operating loss carryforwards to offset current taxable income. 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 the domestic net operating loss carryforward. Upon reaching such a conclusion, and upon such time as we reversed the entire valuation against the deferred tax asset, we would then provide for income taxes at a rate equal to our combined federal and state effective rates. Conversely, we have recorded foreign deferred tax assets of $1,067,000 as a result of losses generated in Italy with no valuation allowance due to the belief that over time, either through operations or available tax planning strategies, we will return to previous levels of profitability that will permit the deferred asset to be realized. Subsequent revisions to the estimated net realizable value of the deferred tax asset could cause our provision for income taxes to vary significantly from period to period. Additionally, if we change or establish valuation reserves against our foreign deferred tax assets, our results of operations could be materially adversely affected.

The critical accounting policies discussed 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 accounting principles generally accepted in the United States, with no need for management's judgment in their application. There are also areas in which management's judgment in selecting any available alternative would not produce a materially different result.

Recently Issued Accounting Standards

On November 24, 2004, the FASB issued SFAS No. 151, *Inventory Costs*, an amendment of ARB No. 43, Chapter 4, which clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material be recognized as current period charges. In addition, this statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. It is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The impact of adoption of this statement is not expected to be significant.

On December 16, 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment,* or SFAS 123(R), which addresses the accounting for transactions in which an entity exchanges its equity instruments for goods or services. This statement focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. It requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. It is effective as of the first interim or annual reporting period that begins after June 15, 2005 and requires companies to expense the fair value of all awards that have future vesting provisions, are modified, or are newly granted beginning on the grant date of such options. The cumulative effect of the initial application of this statement, if any, is to be recognized as of the effective date. SFAS 123(R) can be adopted under two methods,

the modified prospective or the modified retrospective applications. Under the modified prospective application, compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding as of the effective date should be recognized as the requisite service is rendered on or after the effective date. The compensation cost for that portion of awards should be based on the grant-date fair value of those awards as calculated for either recognition or pro forma disclosure under SFAS No. 123. Changes to the grant-date fair value of awards granted before the effective date of this statement are precluded. The compensation cost for those earlier awards should be attributed to periods beginning on or after the effective date of this statement using the attribution method that was used under SFAS No. 123, except that the method of recognizing forfeitures only as they occur should be continued. Any unearned or deferred compensation related to those earlier awards should be eliminated against the appropriate equity accounts. The modified retrospective application may be applied to all prior years that SFAS No. 123 was effective or only to prior interim periods in the year of initial adoption if the effective date of SFAS 123(R) does not coincide with the beginning of the fiscal year. We have not yet determined if we will use the modified prospective or modified retrospective method. The impact of adoption of SFAS 123(R), which may be material, cannot be predicted at this time partly because it will depend on levels of share-based payments granted in the future. However, had we adopted SFAS 123(R) in prior periods, its impact would have approximated the impact of SFAS No. 123 as described in the disclosure of pro forma net income and earnings per share in Note 2, Summary of Significant Accounting Policies, in the Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

Currency Fluctuations

For the years ended December 31, 2004, 2003 and 2002, approximately 36.0%, 33.8% and 34.8%, respectively, of our net revenues were generated in currencies other than the United States dollar. Fluctuations in the value of foreign currencies relative to the United States dollar affect our reported results of operations. If the United States dollar weakens relative to the foreign currency, then our earnings generated in the foreign currency will, in effect, increase when converted into United States dollars and vice versa. Exchange rate differences resulting from the strength or weakness of the United States dollar against the Euro resulted in an increase of approximately $591,000 in net revenues in 2004 compared to 2003 and an increase of approximately $953,000 in net revenues in 2003 compared to 2002. During the three years ended December 31, 2004, no subsidiary was domiciled in a highly inflationary environment. The effects of inflation on consolidated net revenues and operating income were not significant.

Delta represented 36.0% of our net revenues in 2004. 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.

For the three year period ended December 31, 2004, the impact of inflation and changing prices on our net sales and revenues and on income from continuing operations was not material.

Income Taxes

We recognized an income tax (benefit) provision of $(19,000), $80,000 and $(126,000) for the three years ended December 31, 2004, 2003 and 2002, respectively, which related to foreign operations. Through March 14, 2001, we reported our domestic income taxes as part of a consolidated group with IVAX. All domestic taxable losses generated prior to that date were utilized by IVAX. Effective March 14, 2001, as a result of the merger between b2bstores.com and the pre-merger Diagnostics, we are no longer included in the consolidated income tax returns of IVAX.

For financial statement purposes, we accounted for income taxes on a stand-alone basis as though we had filed our own income tax returns. Our income tax provisions for the years ended December 31, 2004, 2003 and

2002 were different from the amount computed on the loss before provision for income taxes at the United States federal statutory rate of 35% primarily due to the reversal of the tax impact of domestic taxable losses which include the previously discussed non-deductible stock option compensation expense.

As of December 31, 2004, we had no net domestic deferred tax asset, as domestic net operating losses generated prior to the merger were utilized by IVAX and a full valuation allowance has been established against domestic deferred tax assets generated subsequent to March 14, 2001. The foreign net deferred tax asset was $1,067,000 at December 31, 2004, of which $1,060,000 is included in other current assets and $7,000 is included in other assets in the accompanying consolidated balance sheet. Realization of the net deferred tax asset is dependent upon generating sufficient future foreign taxable income and upon future events occurring which will result in the reversal of the temporary differences. Although realization is not assured, we believe that based upon the composition of the net foreign deferred tax asset and available tax planning strategies, it is more likely than not that we will realize the deferred tax asset through a combination of reaching levels of profitability which will permit the net operating loss to be used and receiving sufficient payments on foreign accounts receivable which will reverse the temporary difference. If we change or establish a valuation allowance against our foreign net deferred tax asset, our results of operations could be materially adversely affected.

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

Market risk represents the risk of loss that may impact our consolidated financial position, results of operations or cash flows. In the normal course of doing business, we are exposed to the risks associated with foreign currency exchange rates and changes in interest rates.

Foreign Currency Exchange Rate Risk. We are exposed to exchange rate risk when our Italian subsidiary enters into transactions denominated in currencies other than its functional currency. For additional information about foreign currency exchange rate risk, see "Currency Fluctuations" in our Management's Discussion and Analysis of Financial Condition and Results of Operation.

Interest Rate Risk. We do not have debt obligations and our investments are current. We believe that our exposure to market risk relating to interest rate risk is not material.

Commodity Price Risk. We do not believe we are subject to any material risk associated with commodity prices.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders
of IVAX Diagnostics, Inc.

We have audited the accompanying consolidated balance sheets of IVAX Diagnostics, Inc. (a Delaware corporation and majority-owned subsidiary of IVAX Corporation) and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2004. Our audits also included the financial statement schedule listed in the Index at Item 15. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements and schedule 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 financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of IVAX Diagnostics, Inc. and subsidiaries at December 31, 2004 and 2003, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic financial statements taken as a whole, presents fairly in all material respects the information set forth therein.

/s/ Ernst & Young LLP
Certified Public Accountants

Miami, Florida,
February 11, 2005

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2004 AND 2003

	2004	2003
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 7,492,885	$ 2,864,839
Marketable securities	4,650,000	12,600,000
Accounts receivable, net of allowances for doubtful accounts of $3,080,952 and $2,897,833, respectively	7,739,548	6,676,910
Inventories, net	5,143,611	4,473,062
Deferred income taxes	1,060,439	884,649
Other current assets	1,143,034	764,711
Total current assets	27,229,517	28,264,171
PROPERTY, PLANT AND EQUIPMENT:		
Land	352,957	352,957
Buildings and improvements	2,575,222	2,472;777
Machinery and equipment	2,942,140	2,641,865
Furniture and fixtures	1,424,347	1,336,431
	7,294,666	6,804,030
Less—Accumulated depreciation	(5,035,848)	(4,676,001)
	2,258,818	2,128,029
OTHER ASSETS:		
Goodwill, net	6,632,986	6,683,461
Equipment on lease, net	719,277	1,205,593
Other	73,627	84,240
	7,425,890	7,973,294
Total assets	$36,914,225	$38,365,494
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Accounts payable	$ 1,207,042	$ 810,694
Accrued expenses	3,029,820	3,119,941
Total current liabilities	4,236,862	3,930,635
OTHER LONG-TERM LIABILITIES	631,391	471,577
Total liabilities	4,868,253	4,402,212
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Common stock, par value $0.01, authorized 50,000,000 shares, issued and outstanding 27,019,829 in 2004 and 27,659,329 in 2003	270,198	276,593
Additional paid-in capital	41,010,041	43,582,346
Accumulated deficit	(8,948,844)	(9,101,104)
Accumulated other comprehensive loss	(285,423)	(794,553)
Total shareholders' equity	32,045,972	33,963,282
Total liabilities and shareholders' equity	$36,914,225	$38,365,494

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

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS
FOR THE YEARS ENDED DECEMBER 31, 2004, 2003 AND 2002

	2004	2003	2002
NET REVENUE	$18,933,468	$17,673,478	$13,841,006
COST OF SALES	7,724,076	7,484,578	7,265,235
Gross profit	11,209,392	10,188,900	6,575,771
OPERATING EXPENSES:			
Selling	5,811,803	5,335,702	4,636,672
General and administrative	4,378,915	4,587,870	4,010,665
Research and development	1,333,079	1,296,734	1,426,578
Total operating expenses	11,523,797	11,220,306	10,073,915
Loss from operations	(314,405)	(1,031,406)	(3,498,144)
OTHER INCOME:			
Interest income	223,230	225,556	465,405
Other income, net	224,775	210,936	76,801
Total other income	448,005	436,492	542,206
Income (loss) before income taxes	133,600	(594,914)	(2,955,938)
INCOME TAX PROVISION (BENEFIT)	(18,660)	79,781	(126,307)
Net income (loss)	$ 152,260	$ (674,695)	$ (2,829,631)
Basic earnings (loss) per common share	$ .01	$ (.02)	$ (.10)
Diluted earnings (loss) per common share	$ .01	$ (.02)	$ (.10)
WEIGHTED AVERAGE SHARES OUTSTANDING:			
Basic	27,341,043	27,589,908	28,487,631
Diluted	28,542,970	27,589,908	28,487,631

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

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2004, 2003 AND 2002

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
	Shares	Amount				
BALANCE, December 31, 2001	28,635,652	$286,356	$44,530,462	$(5,596,778)	$(2,420,137)	$36,799,903
Comprehensive loss:						
Net loss	—	—	—	(2,829,631)	—	(2,829,631)
Translation adjustment	—	—	—	—	871,334	871,334
Comprehensive loss						(1,958,297)
Stock-based compensation from conversion of stock options	—	—	594,600	—	—	594,600
Exercise of stock options	18,000	180	12,960	—	—	13,140
Repurchase of common stock	(1,134,573)	(11,346)	(2,042,468)	—	—	(2,053,814)
BALANCE, December 31, 2002	27,519,079	275,190	43,095,554	(8,426,409)	(1,548,803)	33,395,532
Comprehensive income:						
Net loss	—	—	—	(674,695)	—	(674,695)
Translation adjustment	—	—	—	—	754,250	754,250
Comprehensive income						79,555
Stock-based compensation from conversion of stock options	—	—	222,225	—	—	222,225
Exercise of stock options	140,250	1,403	264,567	—	—	265,970
BALANCE, December 31, 2003	27,659,329	276,593	43,582,346	(9,101,104)	(794,553)	33,963,282
Comprehensive income:						
Net income	—	—	—	152,260	—	152,260
Translation adjustment	—	—	—	—	509,130	509,130
Comprehensive income						661,390
Repurchase of common stock	(657,125)	(6,571)	(2,621,929)	—	—	(2,628,500)
Exercise of stock options	17,625	176	49,624	—	—	49,800
BALANCE, December 31, 2004	27,019,829	$270,198	$41,010,041	$(8,948,844)	$ (285,423)	$32,045,972

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

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2004, 2003 AND 2002

	2004	2003	2002
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	$ 152,260	$ (674,695)	$ (2,829,631)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities—			
Depreciation and amortization	1,183,028	1,111,080	902,323
Provision for losses on accounts receivable	20,063	140,528	171,594
Stock option compensation expense	—	222,225	594,600
Deferred income tax provision (benefit)	(99,521)	160,071	(169,529)
Changes in operating assets and liabilities:			
Accounts receivable	(661,257)	(315,190)	(1,934,739)
Inventories	(509,665)	83,419	640,679
Other current assets	(307,431)	(143,604)	349,650
Other assets	6,816	6,962	(114,068)
Accounts payable and accrued expenses	123,213	(84,553)	226,957
Other long-term liabilities	114,967	24,204	(88,940)
Net cash provided by (used in) operating activities	22,473	530,447	(2,251,104)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Capital expenditures, net	(406,787)	(381,008)	(661,142)
Acquisition of equipment on lease	(325,448)	(716,963)	(563,963)
Purchases of marketable securities	(1,750,000)	(15,300,000)	(9,000,000)
Proceeds from sales of marketable securities	9,700,000	2,700,000	29,950,000
Net assets of business acquired	—	—	(2,211,747)
Net cash provided by (used in) investing activities	7,217,765	(13,697,971)	17,513,148
CASH FLOWS FROM FINANCING ACTIVITIES:			
Exercise of stock options	49,800	265,970	13,140
Change in due to affiliate	—	—	82,000
Repurchase of common stock	(2,628,500)	—	(2,053,814)
Net cash (used in) provided by financing activities	(2,578,700)	265,970	(1,958,674)
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(33,492)	(175,270)	306,138
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	4,628,046	(13,076,824)	13,609,508
CASH AND CASH EQUIVALENTS, beginning of year	2,864,839	15,941,663	2,332,155
CASH AND CASH EQUIVALENTS, end of year	$ 7,492,885	$ 2,864,839	$15,941,663
SUPPLEMENTAL DISCLOSURES:			
Interest paid	$ —	$ —	$ —
Income taxes paid	$ 318,686	$ —	$ —

Year Ended December 31,	**2004**	**2003**	**2002**
Supplemental disclosure of non-cash activities:			
Acquisition of certain assets of product line:			
Fair value of assets acquired	$ —	$ —	$ 2,456,747
Liabilities assumed	—	—	245,000
Net assets acquired	$ —	$ —	$ 2,211,747

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

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1 ORGANIZATION AND OPERATIONS

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

2 SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

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

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting period. The Company's actual results in subsequent periods may differ from the estimates and assumptions used in the preparation of the accompanying consolidated financial statements. Significant estimates include the allowance for doubtful accounts, inventory reserves, litigation accruals, product returns, discounts and allowances, warranty accruals, tax accruals, deferred tax asset valuation allowances and the realization of long-lived assets.

Recently Issued Accounting Standards

On November 24, 2004, the FASB issued SFAS No. 151, *Inventory Costs,* an amendment of ARB No. 43, Chapter 4, which clarifies the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material be recognized as current period charges. In addition, this statement requires that allocation of fixed production overheads to the costs of conversion be based on the normal capacity of the production facilities. It is effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The impact of adoption of this statement is not expected to be significant.

On December 16, 2004, the FASB issued SFAS No. 123 (revised 2004), *Share-Based Payment,* ("SFAS 123(R)") which addresses the accounting for transactions in which an entity exchanges its equity instruments for goods or services. This statement focuses primarily on accounting for transactions in which an entity obtains employee services in share-based payment transactions. It requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. It is effective as of the first interim or annual reporting period that begins after June 15, 2005 and requires companies to expense the fair value of all awards that have future vesting provisions, are modified, or are newly granted beginning on the grant date of such options. The cumulative effect of the initial application of this statement, if any, is to be recognized as of the effective date. SFAS 123(R) can be adopted under two methods, the modified prospective or the modified retrospective applications. Under the modified prospective application, compensation cost for the portion of awards for which the requisite service has not been rendered that are outstanding as of the effective date should be recognized as the requisite service is rendered on or after the effective date. The compensation cost for that portion of awards should be based on the grant-date fair value of those awards as calculated for either recognition or pro forma disclosure under SFAS No. 123. Changes to the grant-date fair value of awards granted before the effective date of this statement are precluded. The

compensation cost for those earlier awards should be attributed to periods beginning on or after the effective date of this statement using the attribution method that was used under SFAS No. 123, except that the method of recognizing forfeitures only as they occur should be continued. Any unearned or deferred compensation related to those earlier awards should be eliminated against the appropriate equity accounts. The modified retrospective application may be applied to all prior years that SFAS No. 123 was effective or only to prior interim periods in the year of initial adoption if the effective date of SFAS 123(R) does not coincide with the beginning of the fiscal year. The Company has not yet determined if it will use the modified prospective or modified retrospective method. The impact of adoption of SFAS 123(R), which may be material, cannot be predicted at this time partly because it will depend on levels of share-based payments granted in the future. However, had the Company adopted SFAS 123(R) in prior periods, its impact would have approximated the impact of SFAS No. 123 as described in the disclosure of pro forma net income and earnings per share in *Stock-Based Compensation Plans* below.

Cash and Cash Equivalents

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

Marketable Securities

Short-term investments in marketable debt securities are auction rate securities with final maturities longer than one year, but with interest rates resetting every 28 or 35 days through an auction mechanism. These short-term marketable securities consist primarily of taxable municipal bonds and government agency securities. It is our intent to maintain a liquid portfolio to take advantage of investment opportunities; therefore, securities are deemed short-term, are classified as available for sale securities and are recorded at cost which approximates market value based on quoted market prices. Realized gains and losses from sales of marketable securities are based on the specific identification method. For the years ended December 31, 2004, 2003, and 2002, realized gains and losses were not material.

The contractual maturity dates of the Company's investments in marketable debt securities at December 31, 2004 range from 2025 to 2042. The expected maturities may differ from contractual maturities because certain borrowers have the right to call or prepay obligations with and without prepayment penalties.

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 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 uncollectible accounts, while subsequent recoveries are netted against provision for doubtful accounts expense. The Company does not charge interest on accounts receivable.

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. Reserves are provided as appropriate to reduce excess or obsolete inventories to the lower of cost or market. Inventories consist of the following:

	December 31,	
	2004	2003
Raw materials	$1,631,079	$1,611,794
Work-in-process	737,282	340,301
Finished goods	2,775,250	2,520,967
Total	$5,143,611	$4,473,062

Property, Plant and Equipment

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

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

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

Depreciation expense related to property, plant and equipment was $326,270, $312,662 and $232,442 for the years ended December 31, 2004, 2003 and 2002, 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—Revenue Recognition)*, less accumulated amortization, consists of the following:

	December 31,	
	2004	2003
Equipment on lease at cost	$5,911,341	$5,302,744
Less—Accumulated amortization	5,192,064	4,097,151
	$ 719,277	$1,205,593

Equipment on lease is amortized over three years. Amortization expense related to equipment on lease was $848,427, $790,085 and $600,760 for the years ended December 31, 2004, 2003 and 2002, respectively.

Long Lived Assets Including Goodwill

Goodwill is reported net of accumulated amortization and consists of the following:

	December 31,	
	2004	2003
Goodwill	$9,083,666	$9,115,214
Less—Accumulated amortization	2,450,680	2,431,753
	$6,632,986	$6,683,461

The following table displays the changes in the carrying amounts of goodwill by operating segment for the years ended December 31:

	Balance 2003	Foreign Exchange	Balance 2004
Domestic	$2,050,290	$ —	$2,050,290
Italian	4,633,171	(50,475)	4,582,696
Consolidated goodwill	$6,683,461	$ —	$6,632,986

In accordance with SFAS 142, *Goodwill and Other Intangible Assets,* the Company performed its annual test of goodwill using a measurement date of December 31, 2004 and no impairments were noted. Amortization expense related to goodwill ceased after the year 2001.

In accordance with SFAS 144, *Accounting for the Impairment or Disposal of Long Lived Assets,* the Company continually evaluates whether events and circumstances have occurred that indicate that the remaining balance of long lived assets, excluding goodwill that is discussed above, may not be recoverable. When factors indicate that long lived assets excluding goodwill may be impaired, the Company uses various methods to estimate future cash flow, including current and projected levels of income, business trends, prospects and market conditions. If the sum of the expected future undiscounted cash flows is less than the carrying amount of the asset, then an impairment loss is recognized based on the excess of the carrying amount over the estimated fair value of the asset. Any impairment amount is charged to operations.

Future events could cause the Company to conclude that impairment indicators exist and that our long lived assets, including goodwill, are impaired. Any resulting impairment loss could have a material adverse impact on the Company's financial condition and results of operations.

Foreign Currencies

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

The Company is exposed to the risk of currency fluctuation, as a significant portion of its operations are in Italy. The Company does not use financial derivatives to hedge either exchange rates or interest rate fluctuations.

Financial Instruments

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

Revenue Recognition

Revenue and the related cost of sales on sales of test kits and instruments are recognized when risk of loss and title passes, which is generally at the time of shipment. Net revenue is comprised of gross revenue less provisions for expected product returns, allowances and discounts. These provisions and discounts totaled

$50,036 for the year ended December 31, 2002. Provisions and discounts for the years ended December 31, 2003 and December 31, 2004 were not significant.

The Company also owns instruments that it places, under "reagent rental" programs common to the industry, for periods of time at customer facilities for testing and usage with the Company's products ("equipment on lease"). The instrument system, utilized by customers to expedite the performance of certain tests, is paid for over an agreed upon contract period by the purchase of test kits. Revenue is recognized ratably over the rental period.

Provision for estimated warranty claims are established by the Company concurrently with the recognition of revenue. Provisions are established in accordance with generally accepted accounting principles based upon consideration of a variety of factors, including actual experience for products during the past several years by product type, the market for the product and projected economic conditions. Actual product returns, allowances and discounts and warranty claims incurred are, however, dependent upon future events. The Company continually monitors the factors that influence product returns, allowances and discounts and warranty claims and makes adjustments to these provisions when management believes that actual amounts may differ from established reserves.

Shipping and handling fees billed to customers are recognized in net revenue. Shipping and handling costs are included in cost of sales.

Research and Development Costs

Research and development costs related to future products are expensed currently.

Stock-Based Compensation Plans

The employees of the Company are eligible to participate in the IVAX 1997 Employee Stock Option Plan as well as the Company's stock option plans. As permissible under SFAS No. 123, *Accounting for Stock-based Compensation,* the Company currently accounts for all stock-based compensation arrangements using the intrinsic value method prescribed by APB Opinion No. 25, *Accounting for Stock Issued to Employees,* as interpreted by FASB Interpretation No. 44, *Accounting for Certain Transactions Involving Stock Compensation,* and discloses pro forma net earnings and earnings per share amounts as if the fair value method had been adopted.

The Company's pro forma net loss and pro forma weighted average fair value of options granted, with related assumptions, assuming the Company had adopted the fair value method of accounting for all stock-based compensation arrangements consistent with the provisions of SFAS No 123, using the Black-Scholes option pricing model, are indicated below for the years ended December 31, 2004, 2003 and 2002.

	2004	2003	2002
Net income (loss) as reported[1]	$ 152,260	$(674,695)	$(2,829,631)
Deduct: Total stock based employee compensation expense determined under fair value based method for all awards	(342,433)	(287,111)	(281,575)
Pro forma net loss	$(190,173)	$(961,806)	$(3,111,206)
Pro forma basic and diluted loss per share	$ (0.01)	$ (0.03)	$ (0.11)
Pro forma weighted average fair value of options granted	$ 4.48	$ 4.24	$ 1.74
Assumptions:			
Expected life (years)	3.0	5.0	5.4
Risk-free interest rate	3.5%	3.5%	3.5%
Expected volatility	74%	99%	99%
Dividend yield	—	—	—

(1) Includes stock based employee compensation cost of $222,225 and $594,600 for the years ended December 31, 2003 and 2002, respectively, which equals the stock-based employee compensation costs which would have been recognized under the fair value provisions of SFAS No. 123 given the Company's historic volatility of 0% at the time of the modification.

Comprehensive Income (Loss)

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

	Year Ended December 31,		
	2004	2003	2002
Net income (loss)	$152,260	$(674,695)	$(2,829,631)
Foreign currency translations adjustment	509,130	754,250	871,334
Comprehensive income (loss)	$661,390	$ 79,555	$(1,958,297)

Earnings (Loss) per Share

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

A reconciliation of the denominator of the basic and diluted earnings (loss) per share computation for the three years ended December 31, 2004 is as follows:

	December 31,		
	2004	2003	2002
Basic weighted average shares outstanding	27,341,043	27,589,908	28,487,631
Effect of diluted securities—			
Stock options and warrants	1,201,927	—	—
Diluted weighted average shares outstanding	28,542,970	27,589,908	28,487,631
Not included in the calculation of diluted earnings (loss) per share because their impact is antidilutive:			
Stock options and warrants outstanding	793,815	2,317,628	2,433,828

Reclassifications

Certain reclassifications have been made to prior year consolidated financial statements to conform to the current year presentation. In the consolidated balance sheets, the Company reclassified from cash and cash equivalents to marketable securities $12,600,000 and $20,950,000 as of December 31, 2003 and 2001 (no reclassification was required as of December 31, 2002), respectively, which resulted in reclassifications to the consolidated statements of cash flows for the years ended December 31, 2003 and 2002.

3 MERGER AND ACQUISITION

On March 14, 2001, b2bstores.com Inc. ("b2bstores.com"), IVAX Corporation ("IVAX") and the pre-merger IVAX Diagnostics, Inc., then a wholly-owned subsidiary of IVAX, consummated a merger (the

"Merger") of the pre-merger Diagnostics into b2bstores.com pursuant to which all of the issued and outstanding shares of the pre-merger Diagnostics were converted into 20,000,000 shares of b2bstores.com stock and b2bstores.com's name was changed to "IVAX Diagnostics, Inc." Prior to the Merger, b2bstores.com was an internet business services company that was a non-operating public shell on the date of the Merger. Net assets of b2bstores.com on the date of Merger were $22,255,107, consisting primarily of cash of $22,285,064. Additionally, as a condition of the Merger, intercompany indebtedness of $9,581,110 existing between IVAX and the pre-merger IVAX Diagnostics was contributed to capital. For accounting purposes, the Merger was accounted for as sale of stock for cash. The historical financial statements prior to the Merger are those of the pre-merger IVAX Diagnostics with retroactive restatement, as if a stock split occurred, to reflect the 20,000,000 shares of b2bstores.com common stock that IVAX received in the Merger as outstanding for all periods presented. Other than for the stock split, the accompanying consolidated financial statements do not reflect any other adjustments that may result from the Merger. Following the Merger, IVAX' 20,000,000 shares of IVAX Diagnostics represented approximately 70% of the issued and outstanding shares of IVAX Diagnostics.

As a result of the Merger, all non-qualified stock options previously granted to employees of the pre-merger Diagnostics under the IVAX Diagnostics, Inc. 1999 Stock Option Plan (see Note 8, *Shareholders' Equity*) were converted into non-qualified stock options to purchase 1,108,795 shares of the Company's common stock. As a result of this conversion, in accordance with APB Opinion No. 25, *Accounting for Stock Issued to Employees*, the total non-cash compensation cost of $2,378,364 was expensed over the vesting term of the options through June 30, 2003. Of this amount, $222,225 and $594,600 were recorded in general and administrative expense in the accompanying consolidated statements of operations for the years ended December 31, 2003 and 2002, respectively.

On March 21, 2002, the Company announced that it had signed a non-binding letter of intent with Sigma Diagnostics, Inc. ("Sigma Diagnostics"), a wholly-owned subsidiary of Sigma-Aldrich Corporation, pursuant to which the Company would acquire certain assets of Sigma Diagnostics' global enzyme immunoassay product line. On May 15, 2002, the Company consummated the acquisition of certain of the assets of the global enzyme immunoassay product line of Sigma Diagnostics for $2,211,747 and the assumption of certain liabilities. The fair value of these assets acquired was $2,456,747 and included reagent and instrumentation inventory as well as enzyme immunoassay instrumentation placed at customer locations. Goodwill was not recorded in this transaction. Since the acquisition date, the Company's results of operations reflect the revenues and expenses associated with the product line. As a result of the consummation of the transaction with Sigma Diagnostics, the Company no longer sells reagents or instrumentation to Sigma Diagnostics, which had marketed such reagents and instrumentation throughout the world under previous agreements with the Company. Instead, the Company now sells such reagents and instrumentation directly to Sigma Diagnostics' former customer base. Selected employees previously affiliated with Sigma Diagnostics, primarily in the field sales, instrument service and technical support areas, joined the Company. As a result of the consummation of the transaction with Sigma Diagnostics, the Company's previous agreements with Sigma Diagnostics were terminated.

4 CONCENTRATION OF CREDIT RISK

The Company performs periodic credit evaluations of its customers' financial condition and provides allowances for doubtful accounts as required.

The Company's accounts receivable are generated from sales made in the United States and Italy. As of December 31, 2004 and 2003, $5,834,665 and $4,721,125, respectively, of total net accounts receivable were due in Italy. At December 31, 2004 and 2003, 64.8% and 59.6% of total net accounts receivable were due from hospitals and laboratories controlled by the Italian government.

The allowance for doubtful accounts was $3,080,952, $2,897,833 and $2,392,553 at December 31, 2004, 2003 and 2002, respectively, and activity for the years then ended was as follows:

	2004	2003	2002
January 1 balance	$2,897,833	$2,392,553	$1,911,395
Provision	20,063	140,528	171,594
Write-offs	(30,104)	(58,830)	(12,094)
Effects of changes in foreign exchange rates	193,160	423,582	321,658
Balance at December 31	$3,080,952	$2,897,833	$2,392,553

Substantially all cash and cash equivalents and marketable securities are presently held at one national securities brokerage firm. Accordingly, the Company is subject to credit risk if this brokerage firm is unable to repay the balance in the account or deliver the Company's securities or if the brokerage firm should become bankrupt or otherwise insolvent. The Company only invests in select money market instruments, municipal securities and corporate issuers.

5 INCOME TAXES

The Company accounts for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes.* Under SFAS No. 109, deferred tax assets or liabilities are computed based upon the difference between the financial statement and income tax basis of assets and liabilities using the enacted marginal tax rate applicable when the related asset or liability is expected to be realized or settled. Deferred income tax expenses or benefits are based on the changes in the asset or liability from period to period. If available evidence suggests that it is more likely than not that some portion or all of the deferred tax assets will not be realized, then a valuation allowance is required to reduce the deferred tax assets to the amount that is more likely than not to be realized. Future changes in such valuation allowance would be included in the provision for deferred income taxes in the period of change. At December 31, 2004 and 2003, the Company has provided a full valuation allowance against its net domestic deferred tax assets because the Company does not believe that it is more likely than not that some portion or all of the deferred tax assets will be realized.

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

	Year Ended December 31,		
	2004	2003	2002
Current:			
Foreign	$ 80,861	$ (80,290)	$ 43,222
Deferred:			
Foreign	(99,521)	160,071	(169,529)
Total	$(18,660)	$ 79,781	$(126,307)

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

	December 31,	
	2004	2003
Current:		
Accounts receivable allowances	$ 1,087,918	$ 1,015,867
Reserves and accruals	409,333	659,711
Capitalized inventory costs	131,969	143,416
Foreign net operating losses	108,432	—
Other	—	(1,949)
Domestic valuation allowance	(677,213)	(932,396)
Deferred income taxes	1,060,439	884,649
Long-Term:		
Depreciation and basis differences on fixed assets	(202,572)	(170,283)
Domestic net operating losses	2,671,500	2,322,450
Other	6,777	12,595
Domestic valuation allowance	(2,468,928)	(2,152,167)
Amount included in "Other assets"	6,777	12,595
Net deferred tax asset	$ 1,067,216	$ 897,244

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:

	Year Ended December 31,		
	2004	2003	2002
Provision (benefit) for income taxes at U.S. Federal statutory rate of 35%	$ 46,760	$(206,942)	$(1,034,578)
Reversal of tax impact of domestic (income) loss due to valuation allowance change	(104,073)	196,859	882,910
Foreign tax rate differential	38,653	89,864	25,361
Provision (benefit) for income taxes	$ (18,660)	$ 79,781	$ (126,307)

The Company's income tax provisions for the years ended December 31, 2004, 2003 and 2002 were different from the amount computed on the loss before provision for income taxes at the statutory rate of 35% primarily due to the non-recognition of the benefits of domestic losses for each of the three years in the period ended December 31, 2004. Domestic losses include non-deductible stock option compensation expense of $222,225 and $594,600 in the years ended December 31, 2003 and 2002, respectively.

As discussed above, the Company has established a full valuation allowance on its net domestic deferred tax assets, which are primarily comprised of net operating loss carryforwards. During the years ended December 31, 2004, 2003 and 2002, the Company increased its valuation allowances by approximately $62,000, $346,000 and $842,000, respectively. Net operating losses generated by the Company after March 14, 2001 total $6,850,000, $4,010,000 of which are available for use prior to their expiration in 2021. Additionally, net operating losses of $1,595,000, $350,000 and $895,000 are available for use prior to their expirations in 2022, 2023 and 2024, respectively. Approximately $1,326,000 of the domestic net operating loss at December 31, 2004, representing $517,000 of the valuation allowance, relates to the benefit of stock options exercised which have not yet been credited to additional paid-in capital. The net operating losses included in the foreign net deferred tax asset expire in 2009.

United States income taxes have not been provided on undistributed earnings of foreign subsidiaries, as such earnings are being retained indefinitely by such subsidiaries for reinvestment. The distribution of these earnings would first reduce the domestic valuation allowance before resulting in additional United States income taxes.

On October 22, 2004, the American Jobs Creation Act of 2004 was signed into law. Management has reviewed the provisions affecting us and has determined that it is not in our best interest to repatriate any foreign earnings at this time. Such earnings will continue to be reinvested into our foreign operations. The principal reason for deciding against repatriation at a low tax rate is the absence of excess cash in our foreign subsidiary.

6 EMPLOYEE BENEFIT PLAN

Beginning after the date of the Merger, the Company established its own 401(k) employee savings plan which allows for pre-tax employee payroll contributions and discretionary employer matching contributions. Matching contributions of $68,000, $69,000 and $61,000 were made into this plan during the years ended December 31, 2004, 2003 and 2002, respectively.

7 ACCRUED EXPENSES

Accrued expenses consist of the following:

	December 31,	
	2004	2003
Payroll costs	$ 723,417	$ 675,885
Taxes	1,700,861	1,812,195
Professional fees	316,942	250,769
Royalties	73,509	147,178
Other	215,091	233,914
	$3,029,820	$3,119,941

8 SHAREHOLDERS' EQUITY

Common Stock

Concurrent with the approval of the Merger discussed in Note 3, *Merger and Acquisition*, the Company amended its certificate of incorporation to increase the number of shares of authorized common stock from 25,000,000 to 50,000,000.

Share Repurchase Program

During May 2002 the Company's Board of Directors approved a program to repurchase up to 1,000,000 shares of the Company's publicly held common stock. In December 2002, the Company's Board of Directors authorized an additional repurchase of up to 1,000,000 shares of the Company's publicly held common stock. The total number of shares of common stock repurchased by the Company during 2002 was 1,134,573, at a total cost, including commissions, of $2,053,814. There were no share repurchases under this program during 2003 or 2004.

During June 2004, the Company purchased and redeemed a total of 657,125 shares of the Company's common stock from a group of three unaffiliated stockholders at an exercise price of $4.00 per share in

accordance with the terms of a previously announced Redemption Agreement. These shares have been retired and have resumed the status of authorized and unissued shares.

Pre-merger Diagnostics and b2bstores.com Employee Options and Stock Purchase Arrangements

In connection with the initial public offering of b2bstores.com, the underwriters' representatives were issued warrants that expire in February 2005 to purchase up to 400,000 shares of the Company's common stock at a price of $13.20 per share. As of December 31, 2004, these warrants remain outstanding.

Employees of the pre-merger Diagnostics were eligible to participate in the IVAX 1997 Employee Stock Option Plan, as amended (the "1997 Plan"), which permits the issuance of options to employees and consultants to purchase shares of IVAX common stock. The 1997 Plan provides that the exercise price of the issued options shall be no less than the fair market value of IVAX' common stock on the date of grant and that the option terms shall not exceed ten years. Since the approval of the Company's 1999 Stock Option Plan (discussed below), no option grants have been made to Company employees from the 1997 Plan. As of December 31, 2004, 18,750 options priced at $11.71 are outstanding and exercisable by Company employees under the 1997 Plan.

On September 30, 1999 the Board of Directors and stockholders of b2bstores.com approved the 1999 Performance Equity Plan (the "Performance Plan"). The Performance Plan authorizes the grant of up to 2,000,000 shares of common stock to key employees, officers, directors and consultants. Both incentive and non-qualified options may be issued under the Performance Plan. As of December 31, 2004, 308,333 options were outstanding from grants made by b2bstores.com under the Performance Plan prior to the consummation of the Merger at prices ranging from $1.81 to $11.50. During the year ended December 31, 2003, 100,000 shares granted prior to the consummation of the Merger were exercised. There were no such exercises during the years ended December 31, 2004 and 2002. Prior to the creation of the Performance Plan, options to purchase an additional 1,000,000 shares of common stock were granted by the Board of Directors of b2bstores.com to certain of its former officers. As of December 31, 2004, 175,000 options at an exercise price of $6.40 were outstanding from this grant.

Stock Option Plans

Effective June 29, 1999, the Board of Directors and the sole stockholder of the pre-merger Diagnostics approved the IVAX Diagnostics, Inc. 1999 Stock Option Plan (the "1999 Plan"). The 1999 Plan permits the issuance of options to employees, non-employee directors and consultants of the Company to purchase up to 2,000,200 shares of the 50,000,000 authorized shares of common stock of the Company. In June and August of 1999, non-qualified options for 1,144,909 shares of common stock (as determined below) were granted with an exercise price of $.73 per share, a vesting schedule of 50% at the end of year 2 and 25% at the end of each of years 3 and 4 and expiration dates ranging from June to August of 2006. At the effective time of the Merger, automatically and without any action on the part of an option holder, the surviving company assumed the 1999 Plan and each outstanding option granted under the 1999 Plan as an option to purchase shares of the surviving company's common stock under the same terms and conditions as the outstanding option. The number of shares issuable upon the exercise of an option under the 1999 Plan proportionately increased by multiplying the number of outstanding options by the exchange ratio of the Merger. The exercise price per share was proportionately decreased by dividing the exercise price by the exchange ratio of the Merger. For the years ended December 31, 2003 and 2002, non-cash compensation was recorded as a result of the conversion of the 1999 Plan into non-qualified stock options to purchase shares of the Company's common stock *(Note 3, Merger and Acquisition)*.

As of December 31, 2004 options for 1,016,795 shares of common stock were outstanding under the 1999 Plan. No options were exercised or terminated under the 1999 Plan during the year ended December 31, 2004.

During the year ended December 31, 2003, 39,000 options were exercised and 2,000 options were terminated. Additionally, during the year ended December 31, 2002, 18,000 options were exercised while 15,000 options were terminated under the 1999 Plan.

As discussed above, on September 30, 1999 the Board of Directors and stockholders of b2bstores.com approved the Performance Plan that authorizes the grant of up to 2,000,000 shares of common stock to key employees, officers, directors and consultants. As of December 31, 2004 options for 589,449 shares of common stock that were granted after the consummation of the Merger were outstanding under the Performance Plan. During the year ended December 31, 2002, 107,900 options to purchase shares of common stock were granted under the Performance Plan while 200 options were terminated. During the year ended December 31, 2003, 35,000 options to purchase shares of common stock were granted under the Performance Plan while 1,250 options were exercised and 8,950 were terminated. Additionally, during the year ended December 31, 2004, 205,349 options were granted under the Performance Plan while 17,625 options were exercised and 15,775 options were terminated.

The following chart summarizes transactions under the Performance Plan for options granted by the Company after the consummation of the Merger and transactions under the 1999 Plan:

	Number of Shares	Weighted Average Exercise Price
Outstanding at January 1, 2002	1,375,795	$1.19
Granted	107,900	2.16
Terminated	(15,200)	0.73
Exercised	(18,000)	0.73
Outstanding at December 31, 2002	1,450,495	1.28
Granted	35,000	5.20
Terminated	(10,950)	2.09
Exercised	(40,250)	0.78
Outstanding at December 31, 2003	1,434,295	1.38
Granted	205,349	6.52
Terminated	(15,775)	2.90
Exercised	(17,625)	2.83
Outstanding at December 31, 2004	1,606,244	$2.01
Options exercisable at December 31, 2004	1,348,845	$1.71

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted Average Remaining Contractual Life	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$0.73	1,016,795	1.5	$0.73	1,016,795	$0.73
$1.35 – $2.40	89,100	4.4	$2.13	64,550	$2.02
$2.88 – $3.00	260,000	3.2	$2.98	72,500	$2.94
$5.20 – $7.12	240,349	8.4	$6.33	195,000	$6.24

9 SEGMENT INFORMATION

The Company's management reviews financial information, allocates resources and manages the business as two segments defined by geographic region. One segment—the domestic region—contains the Company's

subsidiaries in the United States as well as corporate operations. The Company's other segment—the Italian region—contains the Company's subsidiary located in Italy. The information provided is based on internal reports and was developed and utilized by management for the sole purpose of tracking trends and changes in the results of the regions. The information, including the allocations of expense and overhead, was calculated based on a management approach and may not reflect the actual economic costs, contributions or results of operations of the regions as stand alone businesses. If a different basis of presentation or allocation were utilized, the relative contributions of the regions might differ but the relative trends would, in management's view, likely not be materially impacted. The table below sets forth net revenue, income from operations and assets by region.

	Domestic	Italian	Eliminations	Total
December 31, 2004:				
External net sales	$12,112,373	$ 6,821,095	$ —	$18,933,468
Intercompany sales	835,863	216,829	(1,052,692)	—
Net revenue	$12,948,236	$ 7,037,924	$(1,052,692)	$18,933,468
Loss from operations	$ (224,503)	$ (226,883)	$ 136,981	$ (314,405)
Assets	$20,082,250	$16,831,975	$ —	$36,914,225
December 31, 2003:				
External net sales	$11,699,910	$ 5,973,568	$ —	$17,673,478
Intercompany sales	1,279,127	130,503	(1,409,630)	—
Net revenue	$12,979,037	$ 6,104,071	$(1,409,630)	$17,673,478
Loss from operations	$ (944,319)	$ (77,026)	$ (10,061)	$ (1,031,406)
Assets	$22,844,523	$15,520,971	$ —	$38,365,494
December 31, 2002:				
External net sales	$ 8,999,959	$ 4,841,047	$ —	$13,841,006
Intercompany sales	931,346	444,773	(1,376,119)	—
Net revenue	$ 9,931,305	$ 5,285,820	$(1,376,119)	$13,841,006
Loss from operations	$ (3,142,264)	$ (335,116)	$ (20,764)	$ (3,498,144)
Assets	$23,860,368	$13,562,336	$ —	$37,422,704

10 COMMITMENTS AND CONTINGENCIES

Leases

The Company leases office, plant and warehouse facilities under non-cancellable operating leases. Rent expense for the years ended December 31, 2004, 2003 and 2002 totaled $429,803, $403,621 and $286,258, respectively. The future minimum lease payments under non-cancellable capital leases and their related assets recorded at December 31, 2004 and 2003 were not material. The future minimum lease payments under non-cancellable operating leases with initial or remaining terms of one year or more at December 31, 2004, were as follows:

2005	$475,218
2006	265,926
Total minimum lease payments	$741,144

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.

11 RELATED PARTY TRANSACTIONS

IVAX continues to provide certain services to the Company under a cost-plus service agreement. No material payments were made during 2004, 2003 or 2002 under this service agreement.

As a subsidiary of IVAX, both the Company's directors and officers insurance as well as property insurance coverage falls within the scope of IVAX' directors and officers and property insurance policies. During 2004 and 2003, the Company paid $720,000 and $604,000, respectively, to IVAX for premium payments for the Company's directors and officers insurance coverage. Additionally, during the years ended December 31, 2004 and 2003, the Company paid $82,000 and $74,000, respectively, in premiums to IVAX for property insurance coverage.

12 QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following table summarizes selected quarterly data of the Company for the years ended December 31, 2004 and 2003 (in thousands except per share data):

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Full Year
2004					
Net revenue	$4,732	$5,006	$4,583	$4,612	$18,933
Gross profit	2,849	2,970	2,644	2,746	11,209
Income (loss) from operations	45	112	(252)	(219)	(314)
Net income (loss)	19	205	(94)	22	152
Basic and diluted net income (loss) per share	0.00	0.01	(0.00)	0.00	0.01
2003					
Net revenue	$4,444	$4,491	$4,344	$4,394	$17,673
Gross profit	2,432	2,722	2,631	2,404	10,189
Loss from operations	(364)	(287)	(199)	(181)	(1,031)
Net loss	(287)	(108)	(183)	(97)	(675)
Basic and diluted net loss per share	(0.01)	(0.00)	(0.01)	(0.00)	(0.02)

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

As of the end of the period covered by this Annual Report on Form 10-K, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Exchange Act Rule 13a-15. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures are effective in timely alerting them to material information relating to us required to be included in our periodic filings with the Securities and Exchange Commission. That conclusion, however, should be considered in light of the various limitations described below on the effectiveness of those controls and procedures, some of which pertain to most, if not all, business enterprises, and some of which arise as a result of the nature of our business. Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures will prevent all error and all improper conduct. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Due to the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of improper conduct, if any, have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some person or persons, by collusion of two or more people or by management override of the control. Further, the design of any system of controls also is based in part upon assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions or the degree of compliance with the policies or procedures may deteriorate. Due to the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. No significant changes were made in our internal controls or in other factors that could significantly affect these controls subsequent to the date of our Chief Executive Officer's and Chief Financial Officer's evaluation.

Exhibits 31.1 and 31.2 to this Annual Report on Form 10-K are Certifications of our Chief Executive Officer and the Chief Financial Officer which are required under Section 302 of the Sarbanes-Oxley Act of 2002. This Item 9A, Controls and Procedures, is information concerning the evaluation referred to in the Section 302 Certifications and this information should be read in conjunction with the Section 302 Certifications for a more complete understanding of the topics presented.

Under the rules and regulations of the Securities and Exchange Commission, we are currently not required to comply with the requirements of Section 404 of the Sarbanes-Oxley Act of 2002 until we file our Annual Report on Form 10-K for our fiscal year ending December 31, 2006, so long as we continue to meet the definition of a non-accelerated filer, otherwise we will be required to comply for the year ending December 31, 2005. In our Annual Report on Form 10-K for the year ending December 31, 2006, our management will be required to provide an assessment as to the effectiveness of our internal controls and our independent registered public accounting firm will be required to attest as to our management's assessment. The assessment and attestation processes required by Section 404 are new and neither companies nor auditing firms have significant experience in testing or complying with these requirements. Accordingly, we may encounter problems or delays in completing our obligations and receiving an unqualified report on our internal controls by our independent registered public accounting firm.

While we believe that we will be able to timely meet our obligations under Section 404 and that our management will be able to certify as to the effectiveness of our internal controls, there is no assurance that we

will do so. If we are unable to timely comply with Section 404, our management is unable to certify as to the effectiveness of our internal controls or our independent registered public accounting firm is unable to attest to that certification, the price of our common stock may be adversely affected. Even if we timely meet the certification and attestation requirements of Section 404, it is possible that our independent registered public accounting firm will advise us that they have identified significant deficiencies.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS

The following table sets forth information with respect to our directors and certain of our executive officers as of March 18, 2005.

Name	Age	Position
Giorgio D'Urso	69	Chief Executive Officer, President and Director
Duane M. Steele	54	Vice President—Business Development
Mark S. Deutsch	42	Chief Financial Officer and Vice President—Finance
Raul F. Alvarez	55	Vice President—International Marketing and Sales
Phillip Frost, M.D.	67	Chairman of the Board of Directors
Neil Flanzraich	61	Director
Jane H. Hsiao, Ph.D.	57	Director
Glenn L. Halpryn	44	Director
John B. Harley, M.D.	55	Director
Jose J. Valdes-Fauli	53	Director

Set forth below are of the names, ages, positions held and business experience, including during the past five years, of our directors and certain of our executive officers as of March 18, 2005. Officers serve at the discretion of the board of directors. There is no family relationship between any of the directors or executive officers and there is no arrangement or understanding between any director or executive officer and any other person pursuant to which the director or executive officer was selected.

Mr. Giorgio D'Urso, age 69, has served as our President and Chief Executive Officer and as a director since the merger in 2001 and had served in the same capacities with the pre-merger Diagnostics since 1996. He has served as President and Chief Executive Officer of Diamedix since 1993, President of Delta since 1980, and President of ImmunoVision since 1995. He has over 35 years of diagnostics industry experience. Mr. D'Urso founded Delta, and was its Managing Director from 1980 to 1998. From 1976 to 1980, Mr. D'Urso founded and served as the General Manager of Menarini Diagnostici, Florence, Italy, a division of Menarini S.A.S. Mr. D'Urso also founded and supervised Menarini Diagnosticos S.A. in Spain. From 1974 to 1976, Mr. D'Urso served as the Marketing Manager of the diagnostic division of SmithKline & French S.P.A. in Milan, Italy. From 1969 to 1974, Mr. D'Urso served as the Marketing Manager of Laboratori Travenol S.P.A. in Rome, Italy.

Mr. Duane M. Steele, age 54, has served as our Vice President—Business Development since the merger in 2001 and had served in the same capacity with the pre-merger Diagnostics since 1996. He joined Diamedix in 1995 and has over 27 years of diagnostics industry experience. He has served as the Chief Operating Officer of Diamedix since 1997. From 1995 to 1997, he served as Vice President—Business Development of Diamedix. From 1990 to 1994, he served as President and Chief Executive Officer of LaserCharge, Inc. in Austin, Texas. From 1988 to 1989, Mr. Steele was the General Manger of Austin Biological Laboratories, Inc. From 1972 to 1987, Mr. Steele held a variety of positions with Kallestad Diagnostics, Inc., including Senior Vice President.

Mr. Mark S. Deutsch, age 42, has served as Chief Financial Officer and Vice President—Finance since the merger and had served in the same capacities with the pre-merger Diagnostics since 1996. He has served as the Vice President—Finance of Diamedix since 1993 and has 11 years of diagnostics industry experience From 1988 to 1993, Mr. Deutsch held various positions including Accounting Manager of IVAX and Controller of certain subsidiaries of IVAX. From 1985 to 1988, Mr. Deutsch worked for Arthur Andersen & Co. as a Senior Accountant.

Mr. Raul F. Alvarez, age 55, has served as our Vice President—International Marketing and Sales since April 2001. Prior to joining us, Mr. Alvarez was Vice President—International Business of Immucor, Inc. from 1998 to 2001. From 1994 to 1998, he was Vice President—International Business of Gamma Biologicals, Inc. in Houston, Texas.

Dr. Phillip Frost, age 68, has served as Chairman of the Board of Directors since the merger in 2001. He has served as the Chairman of the Board of Directors and Chief Executive Officer of IVAX since 1987. He served as President of IVAX from July 1991 until January 1995. He was the Chairman of the Department of Dermatology at Mt. Sinai Medical Center of Greater Miami, Miami Beach, Florida from 1972 to 1990. He is a director of Continucare Corporation (healthcare), Northrop Grumman Corp. (aerospace) and Ladenburg Thalmann Financial Services, Inc. (financial services). He is Chairman of the Board of Trustees of the University of Miami and a member of the Board of Governors of the American Stock Exchange.

Mr. Neil Flanzraich, age 61, has served as a director since the merger in 2001 and had served as a director of the pre-merger Diagnostics since September 1998. He has served as Vice Chairman and President of IVAX since May 1998 and as a director of IVAX since 1997. He was a shareholder and served as Chairman of the Life Sciences Legal Practices Group of Heller Ehrman White & McAuliffe from 1995 to May 1998. From 1981 to 1994, he served in various capacities at Syntex Corporation (pharmaceuticals), most recently as its Senior Vice President, General Counsel and a member of the Corporate Executive Committee. From 1994 to 1995, after Syntex Corporation was acquired by Roche Holding Ltd., he served as Senior Vice President and General Counsel of Syntex (U.S.A.) Inc., a Roche subsidiary. He is a director of RAE Systems, Inc. (gas detection and security monitoring systems) and Continucare Corporation (healthcare).

Dr. Jane H. Hsiao, age 57, has served as a director since the merger in 2001. She has served as IVAX' Vice Chairman-Technical Affairs and as a director of IVAX since February 1995, as IVAX' Chief Technical Officer since July 1996, and as Chairman, Chief Executive Officer and President of DVM Pharmaceuticals, Inc., IVAX' veterinary products subsidiary, since March 1998. From 1992 until February 1995, she served as IVAX' Chief Regulatory Officer and Assistant to the Chairman, and as Vice President—Quality Assurance and Compliance of IVAX Research, Inc., IVAX' principal proprietary pharmaceutical subsidiary. From 1987 to 1992, Dr. Hsiao was Vice President-Quality Assurance, Quality Control and Regulatory Affairs of IVAX Research, Inc.

Mr. Glenn L. Halpryn, age 44, has served as a director since December 2002. Mr. Halpryn has been Chairman of the Board of Directors and President of Orthodontix, Inc. since April 2001. Mr. Halpryn has also been Chief Executive Officer of Transworld Investment Corporation since June 2001. Since January 1987, Mr. Halpryn has been a portfolio manager of International Venture Capital, Ltd. From 1984 to June 2001, Mr. Halpryn served as Vice President of Transworld Investment Corporation. Since 1984, Mr. Halpryn has been engaged in real estate investment and development activities, including the management, finance and leasing of commercial real estate. From April 1988 through June 1998, Mr. Halpryn was Vice Chairman of Central Bank, a Florida state-chartered bank. Since February 1987, Mr. Halpryn has been the President of United Security Corporation, a broker-dealer registered with the NASD. From June 1992 through May 1994, Mr. Halpryn served as the Vice President, Secretary and Treasurer and as a director of Frost Hanna Halpryn Capital Group, Inc., a "blank check" company whose business combination was effected in May 1994 with Sterling Healthcare Group, Inc.

Dr. John B. Harley, age 55, has served as a director since the merger in 2001. He has held various positions at the University of Oklahoma Health Sciences Center since 1982. In the Department of Medicine, his positions

include Chief of Rheumatology, Allergy and Immunology Section and Vice Chair for Research, George Lynn Cross Research Professor (1999 to present), James R. McEldowney Chair in Immunology and Professor of Medicine (1992 to present), Associate Professor (1986 to 1992), and Assistant Professor (1982 to 1986). Since 1996 Dr. Harley has been an Adjunct Professor in the Department of Pathology. In the Department of Microbiology, Dr. Harley has served as Adjunct Professor (1992 to present), Adjunct Associate Professor (1988 to 1992), and Adjunct Assistant Professor (1983 to 1988). Since 1982, Dr. Harley has also been associated with the Oklahoma Medical Research Foundation's Arthritis and Immunology Program as Program Head (1999 to present), Member (1998 to present), Associate Member (1989 to present), Affiliated Associate Member (1986 to 1989), and Affiliated Assistant Member (1982 to 1986). Dr. Harley has also served as a Staff Physician (1982, 1984 to 1987 and 1992 to present), and a Clinical Investigator (1987 to 1992), Immunology Section, Medical Service at the Veterans Affairs Medical Center, Oklahoma City, Oklahoma. In 1981 and 1982, Dr. Harley was a Postdoctoral Fellow in Rheumatology with the Arthritis Branch of the National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases, National Institute of Health, Bethesda, Maryland. He was also a Clinical Associate at the Laboratory of Immunoregulation, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland from 1979 to 1982. Dr. Harley is also the Secretary of JK Autoimmunity, Inc.

Mr. Jose J. Valdes-Fauli, age 53, has served as a director since December 2002. Mr. Valdes-Fauli has been President and Chief Executive Officer of Beach Bank since 2004. From 1998 to 2003, Mr. Valdes-Fauli was the President and Chief Executive Officer of Colonial Bank—South Florida Region, an affiliate of Colonial BancGroup. Mr. Valdes-Fauli has been involved in the banking industry for 28 years. He is a member of the Florida International University Foundation Board of Directors. He is also Director Emeritus of the Florida Grand Opera and a director of the Bass Museum of Art, the Concert Association of Florida and the Mercy Hospital Foundation. Mr. Valdes-Fauli is also a member of the Advisory Board of New Hope Charities, Inc. and a member of the Miami-Dade County Cultural Affairs Council.

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 common stock and other of our equity securities with the Securities and Exchange Commission and the American Stock Exchange. 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, 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, 2003, except that Duane M. Steele, Mark S. Deutsch, Neil Flanzraich, Glenn L. Halpryn, John B. Harley, M.D., and Jose J. Valdes-Fauli inadvertently filed one late Form 4 in connection with one transaction each.

Audit Committee Members and Financial Expert

The members of the Audit Committee of the Board of Directors are Glenn L. Halpryn and Jose J. Valdes-Fauli. The Board of Directors has determined that our Audit Committee has one "audit committee financial expert" as such term is defined in the applicable regulations of the Securities and Exchange Commission. The Board of Directors determined that Mr. Valdes-Fauli has the attributes, education and experience of an "audit committee financial expert" and that he is "independent" as such term is defined in the applicable regulations of the Securities and Exchange Commission and rules of the American Stock Exchange relating to directors serving on audit committees. We are currently seeking to add a third member to our Audit Committee to replace Jack R. Borsting, Ph.D., who resigned from our Board of Directors and Audit Committee on January 25, 2005, as previously reported in our Current Report on Form 8-K filed on January 31, 2005.

Code of Conduct and Ethics

The 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. Our Code of Conduct and Ethics and our Senior Financial Officer Code of Ethics are posted in the "Investor Relations" section of our Internet web site at www.ivaxdiagnostics.com. If we make an amendment to, or grant a waiver with respect to, any provision of the Senior Financial Officer Code of Ethics, then we intend to disclose the nature of such amendment or waiver by posting it in the "Investor Relations" section of our Internet web site at www.ivaxdiagnostics.com or by other appropriate means as required or permitted under the applicable regulations of the Securities and Exchange Commission and rules of the American Stock Exchange.

ITEM 11. EXECUTIVE COMPENSATION

Executive Compensation

The following table contains certain information regarding aggregate compensation paid or accrued by us during 2004, 2003 and 2002 to the Chief Executive Officer and to each of our other highest paid executive officers other than the Chief Executive Officer whose total annual salary and bonus exceed $100,000.

Summary Compensation Table

		Annual Compensation		Long Term Compensation
Name and Principal Position	Year	Salary ($)	Bonus ($)	Shares Underlying Stock Options (#)
Giorgio D'Urso	2004	$348,519	—	—
Chief Executive	2003	$348,519	—	—
Officer	2002	$348,519	—	—
Duane M. Steele	2004	$157,794	—	—
Vice President	2003	$150,280	$10,233	10,233
Business Development	2002	$141,002	—	—
Mark S. Deutsch	2004	$110,385	—	—
Chief Financial	2003	$107,170	$ 5,116	5,116
Officer	2002	$102,065	—	—
Raul F. Alvarez	2004	$110,000(1)	—	—
Vice President	2003	$110,000(1)	—	—
International Sales	2002	$110,000(1)	—	—

(1) Includes a commission that we paid to Mr. Alvarez in the amount of $30,000.

Stock Options

The following table sets forth information concerning stock option grants made during 2004 to the executive officers named in the "Summary Compensation Table."

Stock Option Grants in Fiscal Year 2004

	Individual Grants				Potential Realizable Value At Assumed Annual Rate of Stock Price Appreciation for Option Term	
Name	Shares Underlying Stock Options Granted (#)	% of Total Options Granted to Employees	Exercise Price ($/Sh)	Expiration Date	5%($)	10%($)
Giorgio D'Urso	—	—	—	—	—	—
Duane M. Steele	10,233	22.7%	$7.12	March 16, 2011	$29,661	$69,123
Mark S. Deutsch	5,116	11.3%	$7.12	March 16, 2011	$14,829	$34,558
Raul F. Alvarez	—	—	—	—	—	—

The following table sets forth information concerning stock option exercises during 2004 by each of the executive officers named in the "Summary Compensation Table" and the year-end value of unexercised options held by such officers and does not include any stock option exercises for shares of IVAX under the IVAX 1997 Employee Stock Option Plan.

Stock Option Exercises in Fiscal Year 2004 and Fiscal Year-end Option Values

Name	Shares Acquired on Exercise (#)	Value Realized ($)	Number of Shares Underlying Unexercised Stock Options at Fiscal Year-End (#)		Value of Unexercised In-the-Money Stock Options at Fiscal Year-End ($)	
			Exercisable	Unexercisable	Exercisable	Unexercisable
Giorgio D'Urso	—	—	600,000	—	$2,172,000	—
Duane M. Steele	—	—	120,000	60,233	$ 434,400	$67,500
Mark S. Deutsch	—	—	36,000	35,116	$ 130,320	$40,500
Raul F. Alvarez	—	—	18,750	6,250	$ 25,313	$ 8,438

Employment Contracts and Termination of Employment and Change-in-Control Arrangements

On October 1, 1998, the pre-merger Diagnostics entered into a five-year employment agreement with Giorgio D'Urso, President and Chief Executive Officer, at a base annual salary of $348,519, with discretionary annual adjustments. We assumed this employment agreement by operation of law in the merger. Mr. D'Urso's employment may be terminated with or without cause at any time upon written notice. For a termination without cause, we must pay Mr. D'Urso his then current annual base salary in installments for the remainder of the employment term. While employed by us and for a two-year period thereafter, Mr. D'Urso cannot employ or contract with any of our current employees or former employees, except former employees who have not been employed by us for more than one year. We have extended the term of Mr. D'Urso's employment agreement until February 24, 2006.

Compensation Committee Interlocks and Insider Participation

The members of the Compensation and Stock Option Committee of the Board of Directors are Neil Flanzraich, John B. Harley, M.D., and Glenn L. Halpryn. Mr. Flanzraich is also the Vice Chairman of the Board of Directors and President of IVAX.

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

The following table indicates, as of March 18, 2005, information about the beneficial ownership of our common stock by (1) each director, (2) each executive officer named in the "Summary Compensation Table," (3) all directors and executive officers as a group, and (4) each person who we know beneficially owns more than 5% of our common stock. All such shares were owned directly with sole voting and investment power unless otherwise indicated.

Name	Shares (#)[1]	Percent of Class (%)
IVAX Corporation 4400 Biscayne Boulevard Miami, Florida 33137	20,000,000	74.0%
Giorgio D'Urso	628,000[2]	2.3%
Duane M. Steele	122,558[3]	*
Mark S. Deutsch	37,279[4]	*
Raul F. Alvarez	18,750[5]	*
Phillip Frost, M.D.	62,354[6]	*
Neil Flanzraich	35,000[7]	*
Jane Hsiao, Ph.D.	25,000[8]	*
Glenn L. Halpryn	50,000[9]	*
John B. Harley, M.D.	35,000[10]	*
Jose J. Valdes-Fauli	40,000[11]	*
All directors and executive officers as a group (10 persons)	1,053,941	3.9%

* Represents beneficial ownership of less than 1%.

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

(2) Includes options for 600,000 shares of common stock granted to Mr. D'Urso. Also includes options for 8,000 shares of common stock granted to Mr. D'Urso's wife and 5,000 shares of common stock owned by Mr. D'Urso's wife. Mr. D'Urso disclaims beneficial ownership of the stock options and shares of common stock owned by his wife.

(3) Includes options for 122,558 shares of common stock granted to Mr. Steele.

(4) Includes options for 37,279 shares of common stock granted to Mr. Deutsch.

(5) Includes options for 18,750 shares of common stock granted to Mr. Alvarez.

(6) Includes (a) options for 25,000 shares of common stock granted to Dr. Frost and (b) 37,354 shares of common stock owned by Frost Gamma Investments Trust, of which Dr. Frost is the trustee and Frost Gamma, L.P. is the sole and exclusive beneficiary. Dr. Frost is the sole limited partner of Frost Gamma, L.P. The general partner of Frost Gamma, L.P. is Frost Gamma, Inc., and the sole shareholder of Frost Gamma, Inc. is Frost-Nevada Corporation, and the sole shareholder of Frost-Nevada Corporation is Dr. Frost. Does not include any securities owned by IVAX, a corporation in which Dr. Frost is the Chairman of the Board of Directors and Chief Executive Officer and Dr. Frost disclaims beneficial ownership of securities held by IVAX.

(7) Includes options for 35,000 shares of common stock granted to Mr. Flanzraich.

(8) Includes options for 25,000 shares of common stock granted to Dr. Hsiao.

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

(10) Includes options for 35,000 shares of common stock granted to Dr. Harley.

(11) Includes options for 40,000 shares of common stock granted to Mr. Valdes-Fauli.

As of January 1, 2004, 2,085,313 shares of our common stock were available for the granting of stock options under our equity compensation plans.

The following table sets forth information, as of December 31, 2004, with respect to compensation plans (including individual compensation agreements) under which shares of our common stock are authorized for issuance.

Equity Compensation Plan Information

Plan category	(a) Number of shares to be issued upon exercise of outstanding stock options	(b) Weighted-average exercise price of outstanding stock options	(c) Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
Equity compensation plans approved by stockholders	1,914,577	$2.60	1,895,739
Equity compensation plans not approved by stockholders	175,000	$6.40	0
Total	2,089,577	$2.92	1,895,739

As of December 31, 2004, 175,000 options at an exercise price of $6.40 were outstanding under a grant made by b2bstores in September 1999, prior to b2bstores' adoption of the 1999 Performance Equity Plan. These options, which expire on March 13, 2006, are fully vested and exercisable. Upon exercise of these options, the option holder must pay to us the exercise price in cash or by check, bank draft or money order. Upon the occurrence of certain corporate events affecting shares of our common stock, our Compensation and Stock Option Committee is required to make equitable and proportionate adjustments to the number and kind of shares covered by, and the exercise price of, these options. Upon our dissolution, liquidation, merger (in which we are not the surviving corporation) or sale of all or substantially all of our assets, these options will terminate. The option holder is not permitted to assign or transfer these options, except, in the event of the option holder's death, by the laws of descent and distribution or by will.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Upon completion of the merger, we entered into a registration rights agreement with IVAX that requires us to file a registration statement on Form S-3 (at any time after one year, and before the earlier of five years, following the completion of the merger or such time at which all the shares of our common stock owned by IVAX can be sold in any three-month period without registration) to register not less than $1.0 million of our common stock owned by IVAX. Additionally, IVAX may "piggyback" on registrations initiated by us or other holders exercising similar demand registration rights. We may delay the filing of any registration statement for 120 days if we determine in good faith that to effect such registration statement would be detrimental to us or our stockholders. We have agreed to pay all fees and expenses in connection with such registrations, except for any underwriting discounts and commissions. If we file a registration statement in connection with an underwritten offering, IVAX has agreed to sign a customary underwriting agreement in connection with such registration and its rights to register shares is subject to a proration provision if the underwriters determine that the success of the offering will be jeopardized from too many shares being included in the offering. Shares to be sold by us on any registered offering will be included prior to the inclusion of any other shares of our common stock held by IVAX. The registration rights agreement also contains customary mutual indemnification and market stand-off provisions. IVAX can assign or transfer its rights under the registration rights agreement.

In connection with the merger, we entered into a shared services agreement with IVAX pursuant to which IVAX would continue to provide administrative and management services previously provided by IVAX to the pre-merger Diagnostics prior to the merger at IVAX' cost plus 15% for a period of three months. These services include payroll, including printing paychecks and making associated tax filings; treasury, including cash

management services such as disbursements, receipts, banking and investing; insurance, including procuring and administering policies; human resources, including administering employee benefits and plans; financial reporting, including public reports, income taxes; and information systems, including network and website hosting, phone and data systems, software licenses and information systems support.

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

As a subsidiary of IVAX, both our directors and officers insurance as well as property insurance coverage falls within the scope of IVAX' directors and officers and property insurance policies. During 2004 and 2003, we paid $720,000 and $604,000, respectively, to IVAX for premium payments for our directors and officers insurance coverage. Additionally, during 2004 and 2003, we paid $82,000 and $74,000, respectively, in premiums to IVAX for property insurance coverage.

Mary Celli D'Urso, the wife of our Chief Executive Officer and President, has been employed by us for annual compensation of $89,250.

Giulio D'Urso, the son of our Chief Executive Officer and President, has been engaged by our subsidiaries and us for annual compensation of $148,214. Due to currency exchange rate fluctuations, this amount of compensation may vary from year-to-year.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth the aggregate fees billed to us by our independent registered public accounting firm, Ernst & Young LLP, for the fiscal years ended December 31, 2004 and 2003.

	For the Years Ended December 31,	
	2004	2003
Audit Fees	$187,500	$154,000
Audit-Related Fees	—	12,549
Tax Fees	—	—
All Other Fees	—	—
Total Fees	$187,500	$166,549

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 acquisitions; "tax fees" are fees for tax compliance, tax advice and tax planning; and "all other fees" are fees for any services not included in the first three categories.

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

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents Filed as Part of This Annual Report on Form 10-K:

(1) Financial Statements

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

Report of Independent Registered Public Accounting Firm

Consolidated Balance Sheets as of December 31, 2004 and 2003

Consolidated Statements of Operations for the years ended December 31, 2004, 2003 and 2002

Consolidated Statements of Shareholders' Equity for the years ended December 31, 2004, 2003 and 2002

Consolidated Statements of Cash Flows for the years ended December 31, 2004, 2003 and 2002

Notes to Consolidated Financial Statements

(2) Financial Statement Schedules

The following financial statement schedule is filed as a part of this Annual Report on Form 10-K:

Schedule II — Inventory Reserves for the three years ended December 31, 2004

SCHEDULE II

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES
VALUATION AND QUALIFYING ACCOUNTS
THREE YEARS ENDED DECEMBER 31, 2004
(In thousands)

INVENTORY RESERVES

Description	Balance at Beginning of Year	Charged to Cost and Expenses	Net Deductions	Other	Balance at End of Year
Year ended December 31, 2002	$ 295	$ 211	$ (43)	$ 333	$ 796
Year ended December 31, 2003	796	291	(357)	206	936
Year ended December 31, 2004	936	143	(647)	4	436

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

The report of our independent registered public accounting firm with respect to Schedule II is included in its report included in Part II, Item 8 of this Annual Report on Form 10-K.

(b) Exhibits

The following exhibits are either filed as a part of 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 dated June 25, 2002.
3.2	Amended and Restated Bylaws	Incorporated by reference to our Form 10-Q dated August 9, 2002.
4.1	Specimen Common Stock Certificate	Incorporated by reference to our Form 10-K dated April 1, 2002.
4.2	Form of Representatives' Warrant Agreement and Form of Representatives' Warrant Certificate	Incorporated by reference to our Form SB-2/A dated January 26, 2000.
4.3	Registration Rights Agreement, dated March 14, 2001, between IVAX Diagnostics, Inc. and IVAX Corporation	Incorporated by reference to our Form 10-K dated April 1, 2002.
10.1	Form of Indemnification Agreement between IVAX Diagnostics, Inc. and each of its directors	Incorporated by reference to our Form 10-K dated March 31, 2003.
10.2	Asset Purchase Agreement, dated May 15, 2002, between IVAX Diagnostics, Inc. and Sigma Diagnostics, Inc.	Incorporated by reference to our Form 10-K dated March 31, 2003.
10.3	Consulting Agreement, dated September, 1999, between IVAX Diagnostics, Inc. and Mario Cossi	Incorporated by reference to our Form 10-K dated April 1, 2002.
10.4	Amendment to Consulting Agreement, dated July 29, 2003, between IVAX Diagnostics, Inc. and Mario Cossi	Incorporated by reference to our Form 10-K dated March 25, 2004.
10.5	Assignment and Royalty Agreement, dated December 12, 1994, between Diamedix Corporation, Mario Cossi and Riccardo Cossi, as amended as of February 1, 1997, September 1, 1999, and February 15, 2001	Incorporated by reference to our Form 10-K dated April 1, 2002.
10.6	Use of Name License Agreement, dated March 14, 2001, between IVAX Diagnostics, Inc. and IVAX Corporation	Incorporated by reference to our Form 10-K dated April 1, 2002.
10.7	Shared Services Agreement, dated March 14, 2001, between IVAX Diagnostics, Inc. and IVAX Corporation	Incorporated by reference to our Form 10-K dated April 1, 2002.
10.8	Employment Agreement, dated October 1, 1998, between IVAX Diagnostics, Inc. and Giorgio D'Urso	Incorporated by reference to our Form 10-K dated April 1, 2002.

Exhibit Number	Description	Method of Filing
10.9	Amendment to Employment Agreement, dated February 24, 2004, between IVAX Diagnostics, Inc. and Giorgio D'Urso	Incorporated by reference to our Form 10-K dated March 25, 2004.
10.10	1999 Performance Equity Plan	Incorporated by reference to our Form SB-2 dated October 6, 1999.
10.11	1999 Stock Option Plan	Incorporated by reference to our Form 10-K dated April 1, 2002.
10.12	Form of Nonqualified Stock Option Agreement (Employee)	Filed herewith.
10.13	Form of Nonqualified Stock Option Agreement (Non-Employee Director)	Filed herewith.
21.1	Subsidiaries of IVAX Diagnostics, Inc.	Filed herewith.
23.1	Consent of Independent Registered Public Accounting Firm	Filed herewith.
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	Filed herewith.
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith.
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Filed herewith.

SIGNATURES

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

IVAX DIAGNOSTICS, INC.

Dated: March 31, 2005

By: /s/ GIORGIO D'URSO
Giorgio D'Urso,
Chief Executive Officer
and President

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Name	Capacity	Date
/s/ GIORGIO D'URSO **Giorgio D'Urso**	Chief Executive Officer, President and Director (Principal Executive Officer)	March 31, 2005
/s/ MARK S. DEUTSCH **Mark S. Deutsch**	Chief Financial Officer, and Vice President—Finance (Principal Financial Officer) (Principal Accounting Officer)	March 31, 2005
/s/ PHILLIP FROST, M.D. **Phillip Frost, M.D.**	Chairman of the Board of Directors	March 31, 2005
/s/ NEIL FLANZRAICH **Neil Flanzraich**	Director	March 31, 2005
/s/ JANE HSIAO, PH.D. **Jane Hsiao, Ph.D.**	Director	March 31, 2005
/s/ GLENN L. HALPRYN **Glenn L. Halpryn**	Director	March 31, 2005
/s/ JOHN B. HARLEY, M.D. **John B. Harley, M.D.**	Director	March 31, 2005
/s/ JOSE J. VALDES-FAULI **Jose J. Valdes-Fauli**	Director	March 31, 2005

We have made forward-looking statements, which are subject to risks and uncertainties, in this annual report. Forward-looking statements may be preceded by, followed by, or otherwise include the words "may," "will," "believe," "expect," "anticipate," "intend," "plan," "estimate," "project," "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 them and are subject to a number of risks and uncertainties, including, but not limited to, the risks and uncertainties associated with: our implementation, and the progression, of our business model; our ability to maintain profitability; improved financial performance or results not occurring; the volume and efficiency of our production not continuing or not increasing; achieving improved production efficiencies through our implementation of manufacturing automation initiatives; the expansion of our installed base of instrumentation at customer sites not continuing or not driving sales of our reagent kits; our ability to achieve cost advantages from our own manufacture of instrument systems, reagents and test kits; our development and commercial release of our new proprietary automated testing system, named the PARSEC™ System; our ability to receive regulatory approval for the PARSEC™ System; the PARSEC™ System not being available when, or not performing as, expected; the ability of the PARSEC™ System to expand our market presence, particularly in markets and test sectors in which we do not currently compete, including the hepatitis market; the ability of the PARSEC™ System to be a factor in our growth; our ability to market the PARSEC™ System; our customers' integration of the PARSEC™ System into their operations; our ability to manufacture a full panel of hepatitis assays, to obtain regulatory approval for these assays and to include these assays in the menu offered with the PARSEC™ System; the success of our Mago® Plus automation program; the expansion of the testing capability of the Mago® Plus by incorporating IFA testing; the ability of users of the Mago® Plus to simultaneously perform ELISA and IFA testing; our ability to make the Mago® Plus a more competitive analyzer and to attract new customers as a result thereof; our ability to enhance our distribution network, particularly in Europe; our ability to derive benefits from our new distribution agreements in Europe; political and economic instability and foreign currency fluctuation affecting our foreign operations; our ability to find and enter into strategic relationships, acquisitions and technology agreements; and other factors discussed elsewhere in our periodic filings with the SEC, including, without limitation, our Form 10-K which has been provided as a portion of this annual report. Many of these factors are beyond our control.

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