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Diagnositics, Inc.



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2005 Annual Report

July 14, 2006

To Our Stockholders

2005 was a transitional 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.

As a result of the merger between IVAX Corporation and Teva Pharmaceutical Industries Ltd. on January 26, 2006, Teva is now the majority shareholder of IVAX Diagnostics with ownership of approximately 72% of the outstanding shares of our common stock. Dr. Itzhak Krinsky, the Corporate Vice President for Business Development with Teva, has been appointed as our new Chairman of the Board of Directors. For the full year 2005, revenues increased 4% to \$19,762,000 from \$18,933,000 during the full year 2004. During this same period of 2005, our net loss was \$510,000 compared to net income of \$152,000 for the full year 2004. Although we operated at a loss during 2005, there are many initiatives underway that we believe create a promising future for IVAX Diagnostics.

Our principal new product is the PARSEC™ System, our new proprietary automated testing system. We are currently waiting to launch this system in the United States once we receive FDA 510(k) regulatory clearance. We believe that this will occur later this year and give us the opportunity to place many of these new instrument systems at customer sites and allow us to increase our market share in the autoimmune and infectious disease testing markets. We have already begun commercial placements in Europe and we are experiencing a positive response to our marketing efforts. We expect this unique testing system will be a catalyst for us to expand into additional testing sectors in the future through organic growth and strategic initiatives. A prime example of this strategy is our anticipated entrance into the hepatitis testing market through a strategic alliance that we expect will result in us manufacturing an extensive panel of hepatitis assays at our subsidiary in Italy. Additionally, we have relocated to larger, more efficiently planned facilities near Rome that are the base for our commercial activities in Europe, as well as our manufacturing for our instrumentation systems and our future hepatitis kits. We believe that these larger and more modern facilities will support the growth of our new PARSEC™ System, hepatitis kits, and other new product launches that we have planned.

We are excited about our mission of building IVAX Diagnostics into a dynamic company that can continue to serve our customers, employees, and stockholders well.

A handwritten signature in black ink, appearing to read 'G. D'Urso', with a long horizontal flourish extending to the right.

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, 2005
Commission File Number 1-14798

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

Delaware
(State or other jurisdiction of
incorporation or organization)

11-3500746
(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
(Title of class)

American Stock Exchange
(Name of each exchange
on which registered)

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes No

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. Check one:

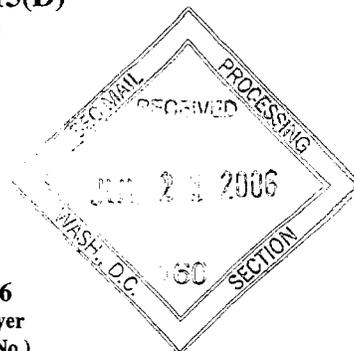
Large accelerated filer Accelerated filer Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The aggregate market value of the voting common stock held by non-affiliates of the registrant on June 30, 2005, was approximately \$33,042,000.

As of March 10, 2006, there were 27,623,554 shares of common stock outstanding.

Documents Incorporated by Reference: None



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IVAX Diagnostics, Inc.
Annual Report on Form 10-K
for the year ended December 31, 2005

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PART I

ITEM 1. BUSINESS

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

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

Through these subsidiaries, we develop, manufacture, and market diagnostic test kits, or assays, and automated systems that are used to aid in the detection of disease markers primarily in the areas of autoimmune and infectious diseases. These tests, which are designed to aid in the identification of the causes of illness and disease, assist physicians in selecting appropriate patient treatment. Most of our tests are based on Enzyme Linked ImmunoSorbent Assay, or ELISA, technology, a clinical testing methodology used worldwide. Specific tests are prepared using a 96 well microplate format whereby specific antigens are typically coated on the wells of a microplate during the manufacturing process. A test using ELISA technology involves a series of reagent additions to the microplate causing a reaction that results in a visible color in the wells. The amount of color is directly proportionate to the amount of the specific analyte in the patient sample. Our kits are designed to be performed either manually or in an automated format. In addition to our line of diagnostic kits, we also design and manufacture laboratory instruments that perform the tests and provide fast and accurate results, while reducing labor costs. Our existing proprietary instruments, named the Mago® 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 final regulatory approval for the PARSEC™ System, nor is it yet available for commercial release in the United States. We also develop, manufacture, and market raw materials, such as antigens used in the production of diagnostic kits.

Our management reviews financial information, allocates resources and manages the business as two segments defined by geographic region. One segment—the domestic region—contains our subsidiaries located in the United States and corporate operations. Our other segment—the Italian region—contains our subsidiary located in Italy. For additional information about our two segments, see Note 10 to our Consolidated Financial Statements.

Delta, which IVAX Corporation, or 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 over 100 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 and support center for selling these same products to distributors located in other European and international markets outside Italy.

Diamedix was established in 1986 after it acquired all of the assets and retained substantially all of the personnel of Cordis Laboratories, Inc., a company that had developed, manufactured, and marketed diagnostic

equipment since 1962. IVAX acquired Diamedix in 1987. Diamedix' products are sold in the United States through Diamedix' sales force. Diamedix markets 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.

Parent Company. On July 25, 2005, IVAX, our approximately 72.4% stockholder, entered into a definitive agreement and plan of merger with Teva Pharmaceutical Industries Limited, or Teva, providing for IVAX to be merged into a wholly-owned subsidiary of Teva. On January 26, 2006, the merger was consummated and IVAX became a wholly-owned subsidiary of Teva for an aggregate purchase price of approximately \$3.8 billion in cash and 123 million Teva ADRs. The transaction was reported to be valued, for accounting purposes, at \$7.9 billion, based on the value of the Teva ADRs during the five trading day period commencing two trading days before the date of the definitive agreement and plan of merger. As a result of the merger, Teva now, indirectly through its wholly-owned IVAX subsidiary, owns approximately 72.4% of the outstanding shares of our common stock.

Market. Our products are primarily associated with the in vitro diagnostics market. In vitro diagnostic assays are tests that are used to detect specific substances, usually either antigens or antibodies, outside the body. This usually involves using a blood sample or other bodily fluid sample for testing. The market for in vitro diagnostic products consists of reference laboratory and hospital laboratory testing, testing in physician offices, and over the counter testing, in which testing can be performed at home by the consumer. Industry analysts have estimated that the world market for in vitro diagnostics was \$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. In

international markets, this line of autoimmune and infectious disease products is supplemented by additional products that are obtained from third party companies.

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 and clinics as well as pharmaceutical and biotechnology research companies. We presented the PARSEC™ System at the American Association for Clinical Chemistry (AACC) Clinical Lab Exposition in Orlando, Florida in July 2005 and the Medica Exhibition in Dusseldorf, Germany in November 2005. We plan to submit a 510(k) application for the PARSEC™ System. As a result, commercial deliveries of the PARSEC™ System in the United States will await regulatory clearance of the 510(k). Commercial activities outside of the United States are not expected to be impacted by this process, and deliveries to customers abroad have already begun and will continue.

Research and Development. We devote substantial resources for research and development. For the years ended December 31, 2005, 2004 and 2003, we spent \$1.8 million, \$1.3 million and \$1.3 million, respectively, for research and development activities.

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 allow us to internally manufacture many of our own hepatitis products with the "CE Marking," as well as internally manufacture our own raw materials for these hepatitis products.

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. A third party payor may deny reimbursement if it determines that a device was not used in accordance with cost-effective treatment methods, was experimental, or for other reasons.

In Italy, as well as in most other countries in Western Europe, our products are sold predominantly to public hospital laboratories, which are managed by government structures either directly or indirectly. In most cases, in Italy, our products are sold through tenders for multiple year periods. Due to the efforts exercised by many governments to contain healthcare costs, there has been a constant effort to consolidate laboratory units and, consequently, the bid process continues to become even more competitive.

On May 15, 2002, we consummated the acquisition of certain of the assets of the global enzyme immunoassay product line of Sigma Diagnostics. 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.

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. 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.

Personnel. As of December 31, 2005, we had approximately 120 full time employees, of whom 15 were managerial, 46 were technical and manufacturing, 12 were administrative, and 47 were sales and marketing.

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

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 Regulation. 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. Class II devices are subject to the same general controls, may be subject to performance standards, and are usually subject to pre-market notification. 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 that were introduced into the marketplace prior to May 1976, or pre-amendment devices. 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 Conformance 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, and plan to update to ISO 13485:2003 in 2006.

Failure to comply with any governmental regulation can result in fines, unanticipated compliance expenditures, interruptions of production, product recalls or suspensions, and criminal prosecution. The process of obtaining regulatory approval is rigorous, time consuming, and costly. In addition, product approvals can be withdrawn if we fail to comply with regulatory standards or if unforeseen problems occur following initial marketing. Domestic and foreign regulations are subject to change and extensive changes in regulation may increase our operating expenses.

We are also subject to numerous federal, state, and local laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and disposal of hazardous or potentially hazardous substances.

Our employment relations in Italy are governed by numerous regulatory and contractual requirements, including national collective labor agreements and individual employer labor agreements. These arrangements address a number of specific issues affecting our working conditions including hiring, work time, wages and benefits, and termination of employment. We must make significant payments in order to comply with these requirements.

Available Information. We file various reports with the Securities and Exchange Commission. We make available, free of charge, through our web site, these reports, including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as soon as reasonably practicable after such documents are electronically filed with or furnished to the Securities and Exchange Commission. Our Internet web site is www.ivaxdiagnostics.com. Information contained in our web site is not part of this Annual Report on Form 10-K and shall not be incorporated by reference herein. Additionally, the public may read and copy any materials we file with the Securities and Exchange Commission at the Securities and Exchange Commission's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. Information on the Public Reference Room may be obtained by calling the Securities and Exchange Commission at 1-800-SEC-0330. The Securities and Exchange Commission also maintains an Internet web site at www.sec.gov that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the Securities and Exchange Commission.

ITEM 1A. RISK FACTORS

You should carefully consider the risks described below. These and other risks could materially and adversely affect our business, operating results or financial condition. The risks described below are not the only risks we face. Additional risks not presently known to us or other factors that we do not presently perceive to present significant risks to us at this time may also impair our operations. You should also refer to the other information contained or incorporated by reference in this Annual Report on Form 10-K.

The future success of our business depends on our development, manufacture and marketing of new products.

Our future success is largely dependent upon our ability to develop, manufacture and market commercially successful new scientific instruments and assays. Delays in the development, manufacture or marketing of new products will impact our operating results and financial condition. Each of the steps in the development, manufacture and marketing of our products, as well as the process taken as a whole, involves significant periods of time and expense. There can be no assurance that:

- any of our products presently under development, if and when fully developed and tested, will perform as expected,
- we will obtain necessary regulatory approvals in a timely manner, if at all, or
- we can successfully and profitably produce and market any of our products.

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

Our strategic initiatives, including our automation strategy, our development and commercial release of our new proprietary instrument system and the expansion of our test kit menu, may not be successful.

Our test kits are designed to be performed either manually or in an automated format. We also design and manufacture our laboratory instruments to perform tests in a fully-automated mode. In furtherance of our automation strategy, we have developed a new proprietary instrument system, named the PARSEC™ System. While deliveries of the PARSEC™ System to customer laboratories abroad have already begun, we intend to seek 510(k) clearance from the FDA for the PARSEC™ System in the United States. Accordingly, commercial deliveries of the PARSEC™ System in the United States will await regulatory clearance of the 510(k). There can be no assurance that we will be able to obtain 510(k) clearance from the FDA for the PARSEC™ System when anticipated or at all. Furthermore, there can be no assurance that our international activities associated with the PARSEC™ System will not be impacted by the delay in the full commercial launch of the PARSEC™ System in the United States.

We expect that the PARSEC™ System will become our primary product and will 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. However, the development and marketing of new or enhanced products is a complex and uncertain process. Accordingly, we cannot be certain that:

- the PARSEC™ System will be available when or perform as expected,
- the PARSEC™ System will become our primary product,
- the PARSEC™ System will enable us to expand the menu of test kits we offer,
- we will be successful in the marketing of the PARSEC™ System, or
- customers will integrate the PARSEC™ System into their operations as readily as expected.

Additionally, in an effort to expand the test kit menu we offer, in September 2004, we entered into a license agreement with an Italian diagnostics company that allows us access to its technology for manufacturing certain hepatitis products. We expect this agreement to enable us to become competitive in markets outside of the United States by providing us with technology that, over time, would allow us to internally manufacture many of our own hepatitis products with the “CE Marking,” as well as internally manufacture our own raw materials for those hepatitis products. However, there remains a risk that we will not be able to obtain product technology that would enable us to manufacture hepatitis products or, if we obtain such product technology, that we will not be able to manufacture hepatitis products or obtain regulatory approval for these products.

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

Our future success depends on the development of new markets.

Our success depends, in large part, on the introduction and acceptance by hospitals, clinics and laboratories of our new diagnostic products and our ability to broaden sales of our existing products to current and new customers. In order to penetrate the market more effectively, we will need to expand our sales and marketing activities by, among other things:

- increasing our sales force,
- expanding our promotional activities,

- developing additional third party strategic distributorships, and
- participating in trade shows.

There is no assurance that these or other activities or programs will be successful. The failure of such activities or programs could have a material adverse effect on our business, prospects, operating results or financial condition.

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

We have sought to differentiate ourselves from our competitors through our proprietary instrument systems. While some of our competitors offer proprietary instruments, other competitors use third-parties to manufacture these instruments for them. We manufacture our Mago® Plus and Aptus® instruments, as well as our new proprietary PARSEC™ System, at Delta, our wholly-owned subsidiary in Italy. Additionally, our wholly-owned subsidiary, ImmunoVision, produces certain autoimmune reagents and our wholly-owned subsidiary, Diamedix, produces diagnostic test kits. There can be no assurance that we will realize cost savings or competitive advantages from our own production of scientific instruments, reagents or test kits.

Our research and development expenditures may not result in commercially successful products.

We devote substantial resources to research and development to update and improve our existing products, as well as to develop new products and technologies. During 2005, we spent approximately \$1.8 million on our research and development efforts. We may in the future increase the amounts we spend on research and development depending upon, among other things:

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

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

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

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

The markets for our products are highly competitive and are characterized by continual and rapid technological developments that have resulted, and will likely continue to result, in substantial improvements in product function and performance. Our success will depend, in part, on our ability to anticipate changes in technology and industry requirements and to respond to technological developments on a timely basis either internally or through strategic alliances. Several companies have developed, or are developing, scientific

instruments and assays that compete or will compete directly with products marketed by us. Many existing and potential competitors have substantially greater financial, marketing, research, and technological resources, as well as established reputations for success in developing, manufacturing, selling and servicing products than us. Competitors that are more vertically integrated than us may have more flexibility to compete effectively on price. We expect that existing and new competitors will continue to introduce products or services that are, directly or indirectly, competitive with those sold by us. Such competitors may succeed in developing products that are more functional or less costly than those sold by us and may be more successful in marketing such products. These and other changes and innovations in the rapidly changing medical technology market may negatively affect the sales of the products we market. There can be no assurance that we will be able to compete successfully in this market or that technology developments by our competitors will not render our products or technologies obsolete. If we fail to effectively compete or adapt to changing technology, it could have a material adverse effect on our business, prospects, operating results or financial condition.

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

Our business is dependent on the active participation of our principal executive officers. The loss of the services of any of these individuals could adversely affect our business and future prospects. In addition, our success is dependent on our ability to retain and attract additional qualified management, scientists, engineers, developers, and regulatory and other personnel. Competition for such talent is intense and there can be no assurance that we will be able to attract and retain such personnel.

Our business is dependent on third-party distributors.

Although our direct sales force consummates the majority of our sales, we also engage third-party distributors to sell our products. In Italy, our products are sold directly through Delta's independent sales force and sales representatives, most of whom work exclusively for Delta. There is no assurance that third-party distributors or independent sales personnel will achieve acceptable levels of sales or that, if any of our existing arrangements expire or terminate, we will be able to replace any distributors or sales personnel on terms advantageous to us, or at all. Further, there is no assurance that we will be able to expand our distribution network by adding additional distributors or sales personnel. If third-party distributors or independent sales personnel cease to promote our products, or if we are unable to make acceptable arrangements with distributors or sales personnel in other markets, our business, prospects, operating results or financial condition could be materially adversely affected.

We depend on our proprietary rights and cannot be certain of their confidentiality and protection.

Our success depends, in large part, on our ability to protect our current and future technologies and products and to defend our intellectual property rights. We have filed several patent applications related to the new innovative features in the PARSEC™ System. However, we cannot be sure that we will receive patents for any of these patent applications or that any patents that we receive will provide competitive advantages for the PARSEC™ System. We also cannot be sure that competitors will not challenge, invalidate or void the application of these patents. In addition, patent rights may not prevent our competitors from developing, using or selling products that are similar or functionally equivalent to our products.

The technology associated with the design and manufacture of the Mago® Plus and Aptus® instruments is not protected by patent registrations or license restrictions. There can be no assurance that our competitors will not gain access to our trade secrets and proprietary and confidential technologies, or that they will not independently develop similar or competing trade secrets and technologies. If others develop competing instruments or other products, then this could erode our competitive advantage and materially harm our business.

We also rely on trade secrets, unpatented proprietary know-how and continuing technological innovation. We use confidentiality agreements with licensees, suppliers, employees and consultants to protect our trade

secrets, unpatented proprietary know-how and continuing technological innovation. There can be no assurance that these parties will not breach their agreements with us. We also cannot be certain that we will have adequate remedies for any breach. Disputes may arise concerning the ownership of intellectual property or the applicability of confidentiality agreements. Furthermore, we cannot be sure that our trade secrets and proprietary technology will not otherwise become known or that our competitors will not independently develop similar or competing trade secrets and proprietary technology. We also cannot be sure, if we do not receive patents for products arising from research, that we will be able to maintain the confidentiality of information relating to our products.

Third parties may claim that we infringe their proprietary rights, which may prevent us from manufacturing and selling some of our products or result in claims for substantial damages.

Technology-based companies are often very litigious and are often subject to unforeseen litigation. Therefore, although our business philosophy is to respect intellectual property rights, we face the risk of adverse claims and litigation alleging infringement of intellectual property rights belonging to others. These claims could result in costly litigation and could divert management's and technical personnel's attention from other matters. The outcome of any claim is difficult to predict because of the uncertainties inherent in litigation. In addition, regardless of the merits of any infringement claims, these claims could cause us to lose our right to develop our discoveries or commercialize our products in certain markets or could require us to pay monetary damages or royalties to license proprietary rights from third parties. Furthermore, we cannot be certain that we would be able to obtain these licenses on terms we believe to be acceptable. As a result, an adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could have a material and adverse effect on our business, prospects, operating results or financial condition.

The trend towards consolidation in the diagnostics industry may adversely affect us.

The diagnostics industry has experienced considerable consolidation through mergers and acquisitions in the past several years. This consolidation trend may result in the remaining companies having greater financial resources and technological capabilities, thereby intensifying competition in the industry, which could have a material adverse effect on our business.

Consolidation of our customers or the formation of group purchasing organizations could result in increased pricing pressure that could adversely affect our operating results.

The health care industry has undergone significant consolidation resulting in increased purchasing leverage for customers and consequently increased pricing pressures on our business. Additionally, some of our customers have become affiliated with group purchasing organizations. Group purchasing organizations typically offer members price discounts on laboratory supplies and equipment if they purchase a bundled group of one supplier's products, which results in a reduction in the number of manufacturers selected to supply products to the group purchasing organization and increases the group purchasing organization's ability to influence its members' buying decisions. Further consolidation among customers or their continued affiliation with group purchasing organizations may result in significant pricing pressures and correspondingly reduce the gross margins of our business or may cause our customers to reduce their purchases of our products thereby adversely affecting our business, prospects, operating results or financial condition.

Additionally, in Italy, and most other countries in Western Europe, our products are sold predominantly to public hospital laboratories, which are managed by government structures either directly or indirectly. In most cases, our products are sold through tenders for multiple year periods. Due to the efforts exercised by many governments to contain healthcare costs, there has been a constant effort to consolidate laboratory units and, consequently, the bid process continues to become even more competitive. The containment of healthcare costs,

consolidation of laboratory units or increase in the competitiveness of the bid process could adversely affect our business, prospects, operating results or financial condition.

Reimbursement policies of third parties could affect the pricing and demand for our products.

Our profitability may be materially adversely affected by changes in reimbursement policies of governmental and private third party payors. The products we market are purchased principally by healthcare providers that typically bill third party payors such as governmental programs (e.g., Medicare and Medicaid), private insurance plans and managed care plans, for healthcare services provided to their patients. Governmental reimbursement policies are subject to rapid and significant changes in the United States, at both the federal and state levels, and in other countries. Private third party payors are increasingly negotiating the prices charged for medical products and services. There can be no assurance that healthcare providers will not respond to such pressures by substituting competitors' products for our products. A third party payor may deny reimbursement if it determines that a device was not used in accordance with cost-effective treatment methods, was experimental, or for other reasons. There can be no assurance that our products will qualify for reimbursement by governmental programs in accordance with guidelines established by the Centers for Medicare and Medicaid Services, by state government payors, or by commercial insurance carriers, or that reimbursement will be available in other countries.

Cost containment measures and health care reform proposals could affect our ability to sell our products.

Various legislative proposals, including proposals relating to the cost containment of healthcare products and the reimbursement policies of governmental and private third party payors, could materially impact the pricing and sale of our products. Reimbursement policies may not include our products. Even if reimbursement policies of third parties grant reimbursement status for a product, we cannot be sure that these reimbursement policies will remain in effect. Limits on reimbursement could reduce the demand for our products. The unavailability or inadequacy of third party reimbursement for our products could reduce or possibly eliminate demand for our products. We are unable to predict whether governmental authorities will enact additional legislation or regulation which will affect third party coverage and reimbursement that reduces demand for our products.

Compliance with governmental regulation is critical to our business.

The products we sell are subject to extensive regulation by numerous governmental and regulatory authorities in the United States, principally the FDA, and other countries. Such regulation includes the regulation of the testing, approval, manufacturing, labeling, marketing and sale of diagnostic devices. Failure to comply with these governmental regulations can result in fines, unanticipated compliance expenditures, interruptions of production and criminal prosecution.

The process of obtaining regulatory approval is rigorous, time consuming and costly. There is no assurance that necessary approvals will be attained on a timely basis, if at all, or at the anticipated cost. In addition, product approvals can be withdrawn if we fail to comply with regulatory standards or if unforeseen problems occur following initial marketing.

In addition, as a general matter, foreign regulatory requirements for medical devices are becoming increasingly stringent. "CE Marking" must be obtained for all medical devices commercially distributed in the European Union, even though the products may have received FDA clearance. In order to be commercially distributed throughout the European Union, certain of our products must bear the "CE Marking." All of the products that we currently sell throughout the European Union are in conformity with the applicable "CE" regulations under the In Vitro Diagnostics Directive. However, if in the future we lose the authorization to use

the “CE Marking,” we may not be able to sell our products in the European Union, which could have a material adverse effect on our business, prospects, operating results and financial condition.

Domestic and foreign regulations are subject to change and extensive changes in regulation may increase our operating expenses. The evolving and complex nature of regulatory requirements, the broad authority and discretion of regulatory authorities and the extremely high level of regulatory oversight result in a continuing possibility that we may be adversely affected by regulatory actions despite our efforts to maintain compliance with regulatory requirements. Delays in obtaining, or the inability to obtain, necessary domestic or foreign regulatory approvals, failures to comply with applicable regulatory requirements or extensive changes in regulation could have a material adverse effect on our business, prospects, operating results or financial condition.

We are subject to a number of regulatory and contractual restrictions governing our relations with our employees in Italy.

Our employment relations in Italy are governed by numerous regulatory and contractual requirements, including, among other things, national collective labor agreements and individual employer labor agreements. These arrangements address a number of specific issues affecting our working conditions, including, without limitation, hiring, work time, wages and benefits, and termination of employment. We must make significant payments in order to comply with these requirements. The cost of complying with these requirements may materially adversely affect our business, prospects, operating results or financial condition.

Our products could fail to perform according to specification, or prove to be unreliable, which could damage our customer relationships and industry reputation and result in lawsuits and loss of sales.

Our customers require demanding specifications for product performance and reliability. Because the products we market are complex and often use state-of-the-art components, processes and techniques, undetected errors and design flaws may occur. Product defects result in higher product service, warranty and replacement costs and may cause serious damage to our customer relationships and industry reputation, all of which will negatively impact our sales and business. We may be subject to lawsuits if any of the products we market fails to operate properly or causes any ailment to be undiagnosed or misdiagnosed.

We may be exposed to product liability claims and there can be no assurance of adequate insurance.

Like all diagnostics companies, the testing, manufacturing and marketing of our products may expose us to product liability and other claims resulting from their use. If any such claims against us are successful, we may be required to make significant compensation payments and suffer the associated adverse publicity. Even unsuccessful claims could result in the expenditure of funds in litigation and the diversion of management time and resources. We believe that we maintain an adequate amount of product liability insurance, but there can be no assurance that our insurance will cover all existing and future claims or that we will be able to maintain existing coverage or obtain additional coverage at reasonable rates. If a claim is not covered or if our coverage is insufficient, we may incur significant liability payments that would have a material adverse effect on our business, operating results or financial condition.

Damages to or disruptions at our facilities could adversely impact our ability to effectively operate our business.

A portion of our facilities, as well as our corporate headquarters and other critical business functions, are located in Miami, Florida—an area subject to hurricane casualty risk. Although we have certain limited protection afforded by insurance, our business and earnings could be materially adversely affected in the event of a major windstorm.

We have limited operating revenue and a history of primarily operational losses.

For the year ended December 31, 2005, we recorded net revenues of \$19.8 million and net loss of \$0.5 million. For the year ended December 31, 2004, we recorded net revenues of \$18.9 million and net income of \$0.2 million. For the year ended December 31, 2003, we recorded net revenues of \$17.7 million and net loss of \$0.7 million. Our principal source of short-term liquidity is, and during the past three years has been, existing cash and cash equivalents and marketable securities received as a result of cash received from the completion of the merger between b2bstores.com and the pre-merger IVAX Diagnostics, which we believe will be sufficient to meet our operating needs and anticipated capital expenditures over 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 we anticipate will be derived primarily from our operations. There is, however, no assurance that existing cash and cash equivalents and marketable securities will satisfy all of our cash requirements and fund any losses from operations. Furthermore, there can be no assurance that we will be able to operate on a profitable basis or internally generate funds from our operations. If existing cash and cash equivalents and marketable securities are insufficient to finance operations or if we are unable to operate on a profitable basis or internally generate funds from our operations, then we may be required to issue securities or incur indebtedness to finance our operations or curtail or reduce our operations.

If we fail to collect our accounts receivable, our operating results could be materially adversely affected.

We maintain an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required payments. As of December 31, 2005 and 2004, our accounts receivable were \$7.7 million and \$10.8 million, respectively, and our allowance for doubtful accounts was \$1.0 million and \$3.1 million. As of December 31, 2005 and 2004, \$5.3 million and \$8.6 million, respectively, of our accounts receivable were due in Italy, and \$0.7 million and \$2.7 million, respectively, of our allowance for doubtful accounts related to Italian accounts receivable. Approximately 90% of Delta's customers in Italy are government owned hospitals and the remaining 10% are private laboratories. As of December 31, 2005 and 2004, 57.0% and 64.8%, respectively, of our net accounts receivable were due from hospitals and laboratories controlled by the Italian government. Accordingly, we are subject to credit risk if the Italian government does not, or is not able to, pay amounts owed to us.

In many instances, our receivables in Italy, while currently due and payable, take in excess of a year to collect and, although untimely, most customers have historically paid the amounts they owe. Nevertheless, there is no assurance that we will collect the outstanding accounts receivable or that the allowance for doubtful accounts will be adequate. The failure to collect outstanding receivables, whether relating to Italy, the United States or elsewhere, could have a material adverse effect on our business, prospects, operating results or financial condition. If the financial condition of our customers was to deteriorate, resulting in an impairment of their ability to make payments, then we may be required to make additional allowances, which would adversely affect our operating results in the period in which the determination or allowance is or was made.

Political and economic instability and foreign currency fluctuations may adversely affect the revenues generated by our foreign operations.

We have a significant wholly-owned subsidiary, Delta, located in Italy. For the years ended December 31, 2005, 2004 and 2003, Delta represented 34.7%, 36.0% and 33.8%, respectively, of our net revenues. Conducting an international business inherently involves a number of difficulties, risks and uncertainties, such as:

- export and trade restrictions,
- inconsistent and changing regulatory requirements,
- tariffs and other trade barriers,
- cultural issues,

- longer payment cycles,
- problems in collecting accounts receivable,
- political instability,
- local economic downturns,
- seasonal reductions in business activity in Europe during the traditional summer vacation months, and
- potentially adverse tax consequences.

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

For the years ended December 31, 2005, 2004 and 2003, 34.7%, 36.0% and 33.8% of our net revenue, respectively, 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 operating results. For instance, if the United States dollar strengthens relative to foreign currency, then our earnings generated in foreign currency will, in effect, decrease when converted into United States dollars, which could have a material and adverse effect on our operating results. We do not use financial derivatives to hedge exchange rate fluctuations.

We may not be able to use inventories of parts and products purchased or made before receiving final regulatory clearance or beginning full commercial marketing.

From time to time, we purchase or make significant quantities of parts and products prior to the date on which we receive final regulatory clearance or begin our full commercial marketing. The production of pre-launch inventories for our products involves the risks, among others, that the parts and products may not be approved for commercial marketing by the applicable regulatory authorities on a timely basis, if at all, or that we may not be able to find alternative uses for such inventory. If any of these events were to occur or the launch of the products is significantly postponed, then we may be required to reassess the net realizable value of the related inventory and could, in such case, incur a charge to write down the value of such inventory, which would adversely affect our operating results in the period in which the determination or charge is or was made.

There are inherent uncertainties involved in estimates, judgments and assumptions used in the preparation of financial statements in accordance with United States GAAP. Any changes in estimates, judgments and assumptions used could have a material adverse effect on our business, financial position and operating results.

The consolidated financial statements included in the periodic reports we file with the Securities and Exchange Commission are prepared in accordance with accounting principles generally accepted in the United States of America, or GAAP. The preparation of financial statements in accordance with GAAP involves making estimates, judgments and assumptions that affect reported amounts of assets (including intangible assets), liabilities and related reserves, revenues, expenses and income. This includes estimates, judgments and assumptions for assessing the recoverability of our goodwill and other intangible assets, pursuant to Statement of Financial Accounting Standards (SFAS) No. 142, *Goodwill and Other Intangible Assets*, and SFAS No. 144, *Accounting for the Impairment or Disposal of Long-Lived Assets*. If any estimates, judgments or assumptions change in the future, we may be required to record additional expenses or impairment charges. Any resulting expense or impairment loss would be recorded as a charge against our earnings and could have a material adverse impact on our financial condition and operating results. Estimates, judgments and assumptions are inherently subject to change in the future, and any such changes could result in corresponding changes to the amounts of assets (including goodwill and other intangible assets), liabilities, revenues, expenses and income. Any such changes could have a material adverse effect on our financial position and operating results.

On an on-going basis, we evaluate our estimates, including, among others, those relating to:

- product returns,
- allowances for doubtful accounts,
- inventories and related reserves,
- intangible assets,
- income and other tax accruals,
- deferred tax asset valuation allowances,
- discounts and allowances,
- warranty obligations, and
- contingencies and litigation.

We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our assumptions and estimates may, however, prove to have been incorrect and our actual results may differ from these estimates under different assumptions or conditions. While we believe the assumptions and estimates we make are reasonable, any changes to our assumptions or estimates, or any actual results which differ from our assumptions or estimates, could have a material adverse effect on our financial position and operating results.

Our potential acquisitions may reduce our earnings, be difficult for us to combine into our operations or require us to obtain additional financing.

In the ordinary course of our business, we evaluate potential business acquisition opportunities that we anticipate will provide new product and market opportunities, benefit from and maximize our existing assets and add critical mass. We often incur significant expenses in connection with our evaluation of potential business acquisition opportunities. However, we may not be successful in finding or consummating any acquisitions, and any acquisitions we make may expose us to additional risks and may have a material adverse effect on our operating results. Any acquisitions we make may fail to accomplish our strategic objectives, may not be successfully combined with our operations or may not perform as expected. In addition, although we generally seek acquisitions that we believe will be accretive to our per share earnings, based on current acquisition prices in the industry, our acquisitions could initially reduce our earnings and add significant intangible assets and related amortization charges. Our acquisition strategy may require us to obtain debt or equity financing, resulting in increased leverage or increased debt obligations, as compared to equity, and the dilution of our stockholders' ownership of us. We may not be able to finance acquisitions on terms satisfactory to us.

The impact of new accounting principles could have a material adverse effect on our operating results or financial condition.

We currently account for stock options granted to employees under Accounting Principles Board Opinion No. 25, *Accounting for Stock Issued to Employees*. Under this standard, no compensation cost is recorded for stock options granted to employees at fair market value on the date of grant. On December 16, 2004, the Financial Accounting Standards Board issued SFAS No. 123 (revised 2004), *Share-Based Payments*, 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. This Statement requires all share-based payments to employees, including grants of employee stock options, to be recognized in the income statement based upon their fair values. We cannot predict the impact, which may be material, of our adoption of this Statement primarily because

the impact will depend on levels of share-based payments in the future. Compensation expense will be required to be recorded for vesting of pre-2006 unvested options and future awards of share-based payments. This Statement and other new accounting principles adopted in the future may have a material adverse effect on our financial condition or operating results.

We will be exposed to risks relating to evaluations of internal control over financial reporting required by Section 404 of the Sarbanes-Oxley Act of 2002.

We anticipate spending a substantial amount of management time and resources to comply with changing laws, rules, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, regulations promulgated by the Securities and Exchange Commission and rules promulgated by the American Stock Exchange.

Under the current 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, 2007, so long as we continue to meet the definition of a non-accelerated filer. In our Annual Report on Form 10-K for the year ending December 31, 2007, management will be required to provide an assessment as to the effectiveness of our internal control over financial reporting and our independent registered public accounting firm will be required to attest as to management's assessment and to the effectiveness of internal control over financial reporting. The assessment and attestation processes required by Section 404 are relatively 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 control over financial reporting by our independent registered public accounting firm.

While we believe that we will be able to timely meet our obligations under Section 404 and that management will be able to certify as to the effectiveness of our internal controls, there is no assurance that we will do so. The price of our common stock may be adversely affected if:

- we are unable to timely comply with Section 404,
- 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.

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 and/or material weaknesses, which may also adversely affect the price of our common stock.

Substantially all of our cash and cash equivalents and marketable securities are held at a single brokerage firm.

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. Any of the above events could have a material and adverse effect on our business and financial condition.

Teva, indirectly through its wholly-owned IVAX subsidiary, controls our company.

Teva, indirectly through its wholly-owned IVAX subsidiary, owns approximately 72.4% of the issued and outstanding shares of our common stock. Under our certificate of incorporation, on issues for which our stockholders are eligible to vote, the affirmative vote of a majority of the shares represented at a meeting in person or by proxy, and entitled to vote, is required to approve an action. Consequently, Teva can unilaterally approve actions that require stockholder approval and elect directors acceptable to it based on its share ownership.

We may have conflicts of interest with Teva.

Conflicts of interest may arise between Teva and us in a number of areas relating to past matters with IVAX and ongoing matters with Teva, including, without limitation, labor, tax, employee benefits, indemnification, intellectual property, employee retention and recruiting, major business combinations, Teva's sale or distribution of all or any portion of its ownership interest in us, the nature, quality and pricing of the administrative services Teva provides or IVAX has provided to us, and business opportunities that might be attractive to both Teva and us. Teva may decide to compete with us in the future, which would create an additional conflict of interest. Three of the former executive officers of IVAX, certain of whom are now employees of Teva, are members of our board of directors. For as long as Teva controls us, Teva will be able to require us to agree to amend any agreements we have with IVAX or will have with Teva, even if those amendments are less favorable to us than the current terms of any such agreement. We cannot guarantee that any conflicts that may arise will be resolved in a matter that is favorable to us. Additionally, even if we do resolve such conflicts, the resolutions may be less favorable to us than it would be if we were dealing with an unaffiliated third party.

Many of our directors have, and certain of our officers and employees may have, a substantial amount of their personal financial portfolios in Teva ADRs. Potential conflicts of interests may arise if those directors or officers are faced with decisions that could have different implications for Teva and us. Additionally, our financial results will be included in Teva's consolidated financial statements for so long as Teva continues to own at least 50% of our common stock. Our directors who may hold positions with Teva, and who may also be holders of Teva ADRs, may therefore consider not only the short-term and long-term impact of financial and operating decisions on us, but also the impact of these decisions on Teva's consolidated financial results and stockholders. In some instances, these decisions could be disadvantageous to us and advantageous to Teva.

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

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

In 2001, we entered into a use of name license agreement with IVAX whereby IVAX granted us a non-exclusive, royalty free license to use the name "IVAX." IVAX may terminate this license at any time upon 90 days written notice. There can be no assurance that IVAX will not terminate this license agreement. Upon termination of the agreement, we are required to take all steps reasonably necessary to change our name as soon as practicable. The termination of this agreement could have a material adverse effect on our business, prospects, operating results or financial condition.

Our stock has a limited trading volume and a number of internal and external factors have caused, and may continue to cause, the market price of our stock to be volatile.

Our common stock has only been listed and traded on the American Stock Exchange since March 15, 2001. As a result of Teva, through its wholly-owned IVAX subsidiary, owning approximately 72.4% of the issued and outstanding shares of our common stock, we have a limited non-affiliate market capitalization. As a result, our common stock has a limited trading volume, which makes it more difficult for our stockholders to sell their shares.

Additionally, the market prices for securities of companies engaged in the healthcare field, including us, have been volatile. Many factors, including many over which we have no control, may have a significant impact on the future market price of our common stock, including, without limitation:

- announcements by us and our competitors of technological innovations, new commercial products or significant contracts or business acquisitions,
- period-to-period changes in our financial results,

- market acceptance of existing or new products,
- the financial results of, and announcements made by and actions taken by, Teva, and
- changes in general conditions in the economy, financial markets or healthcare industry.

The issuance of preferred stock or additional shares of common stock could adversely affect the rights of the holders of shares of our common stock.

Our board of directors is authorized to issue up to 5,000,000 shares of preferred stock without any further action on the part of our stockholders. Currently, we have no shares of preferred stock outstanding. In the event that we issue preferred stock in the future that has preference over the common stock with respect to payment of dividends or upon our liquidation, dissolution or winding up, the rights of holders of shares of our common stock may be adversely affected. In addition, the ability of our board of directors to issue shares of preferred stock without any further action on the part of our stockholders may impede a takeover of us and may prevent a transaction that is favorable to our stockholders.

Cautionary Statement Concerning Forward-Looking Statements

We have made forward-looking statements, which are subject to risks and uncertainties, in this Annual Report on Form 10-K. 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 impact of the delay in the full commercial launch of the PARSEC™ System in the United States on our international activities associated with the PARSEC™ System;
- the ability of the PARSEC™ System to be available when or perform as expected;
- 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 ability to update to ISO 13485:2003;

- 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, 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;
- our ability to sell the current location of our Miami facility and to acquire a new location to which to relocate it;
- protecting our intellectual property;
- political and economic instability and foreign currency fluctuation affecting our foreign operations;
- the 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 Teva;
- conflicts of interest with Teva, 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 2. PROPERTIES

Our corporate headquarters are located in Miami, Florida. Our corporate headquarters share facilities with Diamedix, which owns approximately 56,000 square feet of buildings at its facility in Miami, Florida. From this

facility, Diamedix conducts research and development of in vitro diagnostic products, reagent kit manufacturing, marketing, and corporate management activities.

Delta leases approximately 56,000 square feet of industrial space in Pomezia, Italy, which houses warehouse, production and commercial office facilities. This facility is where our proprietary instrumentation is manufactured. ImmunoVision leases approximately 5,700 square feet of commercial space in Springdale, Arkansas.

We believe our facilities are in satisfactory condition, are suitable for their intended use and, in the aggregate, have capacities in excess of those necessary to meet our present needs.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. 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, 2005.

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 20, 2006, there were approximately 55 holders of record of our common stock.

The following table sets forth the high and low sales prices of a share of our common stock for each quarter in 2005 and 2004, as reported by the American Stock Exchange:

	<u>High</u>	<u>Low</u>
2005		
Fourth Quarter	\$4.26	\$3.01
Third Quarter	4.70	3.50
Second Quarter	4.99	3.51
First Quarter	4.36	3.13
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

We did not declare or pay cash dividends on our common stock during 2005 or 2004 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, 2005, 2004, 2003, 2002 and 2001 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,				
	2005	2004	2003	2002	2001
(In thousands except per share data)					
Consolidated Statement of Operations Data:					
Net Revenue	\$19,762	\$18,933	\$17,673	\$13,841	\$10,299
Income (loss) from operations ⁽¹⁾	\$ 277	\$ (314)	\$ (1,031)	\$ (3,498)	\$ (3,874)
Net income (loss) ⁽¹⁾	\$ (510)	\$ 152	\$ (675)	\$ (2,830)	\$ (3,509)
Net income (loss) per basic and diluted common share ⁽¹⁾	\$ (.02)	\$.01	\$ (.02)	\$ (.10)	\$ (.13)
Weighted average number of shares outstanding					
Basic	27,295	27,341	27,590	28,488	26,879
Diluted	27,295	28,543	27,590	28,488	26,879
As of December 31,					
(In thousands)					
Balance Sheet Data:					
Working capital	\$20,036	\$22,993	\$24,334	\$23,521	\$27,812
Total assets	\$35,904	\$36,914	\$38,365	\$37,423	\$40,147
Total liabilities	\$ 5,714	\$ 4,868	\$ 4,402	\$ 4,027	\$ 3,347
Total stockholders' equity	\$30,190	\$32,046	\$33,963	\$33,396	\$36,800

(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 year ended December 31, 2001 does not reflect 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 35 to 56 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 over 100 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 and support center for selling these same products to distributors located in other European and international markets outside Italy.

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.

Majority Stockholder

On July 25, 2005, IVAX, our approximately 72.4% stockholder, entered into a definitive agreement and plan of merger with Teva providing for IVAX to be merged into a wholly-owned subsidiary of Teva. On January 26, 2006, the merger was consummated and IVAX became a wholly-owned subsidiary of Teva for an aggregate purchase price of approximately \$3.8 billion in cash and 123 million Teva ADRs. The transaction was reported to be valued, for accounting purposes, at \$7.9 billion, based on the value of the Teva ADRs during the five trading day period commencing two trading days before the date of the definitive agreement and plan of merger. As a result of the merger, Teva now, indirectly through its IVAX subsidiary, owns approximately 72.4% of the outstanding shares of our common stock.

Results of Operations

Year Ended December 31, 2005 Compared to the Year Ended December 31, 2004

Overview

Net loss in 2005 was \$510,000 compared to net income in 2004 of \$152,000, while operating income was \$277,000 in 2005 compared to an operating loss of \$314,000 in 2004. Revenue increased \$829,000 to a record level of \$19,762,000 in 2005, with a corresponding gross profit increase of \$460,000 to \$11,669,000 in 2005, primarily due to volume increases in domestic reagent revenue as well as an increase in international antigen sales. Additionally, income from operations significantly improved due to a \$860,000 reduction in general and

administrative expenses, caused principally by the \$1,690,000 bad debt recovery recorded when we reduced our allowance for doubtful accounts to recognize the impact of the May 12, 2005 collection of previously outstanding Italian accounts receivable from hospitals located within a particular region in Italy. Partially offsetting this reduction in general and administrative expenses was a \$580,000 charge to general and administrative expenses for compensation expense and related payroll taxes recorded as a result of our cancellation of 499,398 options to purchase shares of our common stock, which were granted under our 1999 Stock Option Plan, in exchange for a payment to participating option holders pursuant to the previously disclosed July 2005 program that we had offered. The overall decrease in our general and administrative expense was partially offset by an increase of \$295,000 in selling expenses as well as an increase of \$433,000 in research and development expenses related to the PARSEC™ System. Our tax provision in 2005 was \$1,077,000 compared to a tax benefit of \$19,000 in 2004, with the increase primarily due to the recognition of deferred taxes in 2005 related to the impact of the collection of previously outstanding Italian accounts receivable and the creation of a valuation allowance to fully reserve the remaining foreign net deferred tax assets. Additionally, in 2005, other income decreased \$158,000 from 2004.

Net Revenues and Gross Profit

	<u>2005</u>	<u>2004</u>	<u>Period over Period Increase (Decrease)</u>
Net Revenues Excluding Intercompany Sales			
Domestic	\$12,897,000	\$12,112,000	\$785,000
Italian	<u>6,865,000</u>	<u>6,821,000</u>	<u>44,000</u>
Total	19,762,000	18,933,000	829,000
Cost of Sales	<u>8,093,000</u>	<u>7,724,000</u>	<u>369,000</u>
Gross Profit	<u>\$11,669,000</u>	<u>\$11,209,000</u>	<u>\$460,000</u>
% of Total Net Revenues	59.0%	59.2%	

Net revenues in 2005 increased \$829,000, or 4.4%, from 2004. This increase was comprised of increases in external net revenues of \$785,000 from domestic operations and \$44,000 from Italian operations. Domestic external net revenues in 2005 increased by 6.5% from 2004. This increase was primarily due to greater revenue derived from volume increases in domestic reagent and international antigen revenue, partially offset by reductions caused by year-end backorders of certain diagnostic test kits and decreased revenue from a lower volume of instrument sales. The slight increase in external net revenues from Italian operations was primarily attributable to volume increases in reagent sales that were substantially offset by price reductions. Revenue fluctuations of the United States dollar relative to the Euro, as further discussed in "Currency Fluctuations" below, were insignificant. Gross profit in 2005 increased \$460,000, or 4.1%, from the prior year and was primarily attributable to the increase in net revenues. Gross profit as a percentage of net revenues was relatively unchanged in 2005 compared to 2004. The positive trends of an increase in manufacturing efficiencies gained from an increase in domestic reagent and international antigen revenue, as well as a decrease in expenses related to the amortization of equipment on lease, were offset by increased labor and regulatory consulting costs incurred in 2005 in an effort to improve our domestic production and quality operations.

Operating Expenses

	<u>2005</u>	<u>% of Revenue</u>	<u>2004</u>	<u>% of Revenue</u>	<u>Period over Period Increase (Decrease)</u>
Selling Expenses					
Domestic	\$ 3,621,000	18.3%	\$ 3,529,000	18.6%	\$ 92,000
Italian	<u>2,486,000</u>	12.5%	<u>2,283,000</u>	12.1%	<u>203,000</u>
Total	6,107,000	30.9%	5,812,000	30.7%	295,000
General and Administrative	3,519,000	17.8%	4,379,000	23.1%	(860,000)
Research and Development	<u>1,766,000</u>	8.9%	<u>1,333,000</u>	7.0%	<u>433,000</u>
Total Operating Expenses	<u>\$11,392,000</u>	57.6%	<u>\$11,524,000</u>	60.9%	<u>\$(132,000)</u>

The most significant variation in operating expenses occurred as general and administrative expenses decreased by \$860,000 principally as a result of a bad debt recovery of Italian accounts receivable resulting from the impact of a May 12, 2005 payment of previously outstanding accounts receivable balances from hospitals located within a particular region in Italy. A significant portion of this approximately 2,000,000 Euro payment related to accounts receivable against which we had previously established allowances. As a result, we recognized a \$1,690,000 bad debt recovery, which is included in general and administrative expenses, as we reduced our allowance for doubtful accounts to recognize the impact of this collection of these receivables. Partially offsetting this reduction in general and administrative expenses was approximately \$580,000 in domestic compensation expense and related payroll taxes recorded as a result of our cancellation of 499,398 options to purchase shares of our common stock, which were granted under our 1999 Stock Option Plan, in exchange for a payment to participating option holders pursuant to a July 2005 program that we had offered, as further described in "Liquidity and Capital Resources" below. Partially offsetting the decrease in general and administrative expenses was an increase of \$295,000 in selling expenses in 2005 compared to 2004. The increase of \$203,000 in the Italian portion of selling expenses was primarily due to the effect of increased payroll and consulting costs principally due to the marketing and promotion of the PARSEC™ System. Domestic selling expenses increased \$92,000, primarily as a result of increased instrumentation and technical service costs, partially offset by lower sales force payroll costs. Research and development expenses increased \$433,000 due to an increase in Italian research and development expenses to \$888,000 in 2005 from \$539,000 in 2004, along with an increase in domestic research and development expenses to \$878,000 in 2005 from \$794,000 in 2004. The increase in research and development expenses was primarily the result of increased Italian research and development expenses related to the PARSEC™ System, principally due to increased consulting and payroll 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.

Income (Loss) from Operations

Income from operations was \$277,000 in 2005 compared to a net loss from operations of \$314,000 in 2004. Excluding intersegment elimination adjustments, which decreased consolidated income from operations by \$8,000, income from operations in 2005 was composed of income from Italian operations of \$971,000, which includes the effect of the bad debt recovery of Italian accounts receivable in May 2005, offset by a loss from domestic operations of \$686,000, which includes the effect of the compensation expense relating to our cancellation of stock options pursuant to our July 2005 program. Excluding intersegment elimination adjustments, which decreased consolidated loss from operations by \$137,000, the loss from operations in 2004 was composed of a loss from domestic operations of \$224,000 and a loss from Italian operations of \$227,000.

Other Income, Net

Interest income increased to \$352,000 in 2005 from \$223,000 in 2004 primarily due to higher interest rates. Other expense, net totaled \$62,000 during 2005, compared to other income, net of \$225,000 in 2004. Amounts included in other income, net in 2005 and 2004 were primarily net foreign currency gains and losses on transactions, particularly by our Italian subsidiary, which were denominated in currencies other than a subsidiary's functional currency.

Income Tax Provision

During 2005 we recorded an income tax provision of \$1,077,000 compared to an income tax benefit of \$19,000 in 2004. The tax provision in 2005 was recognized by our Italian operation and is composed primarily of deferred taxes related to the allowance for doubtful accounts that was reduced during the first quarter of 2005 as a result of the May 12, 2005 collection of certain previously reserved Italian accounts receivable and the creation of a valuation allowance to fully reserve the remaining foreign net deferred tax assets. The tax benefit in 2004

was realized by our Italian operation as a result of before tax losses in Italy. No domestic tax provision was recorded in 2005 due to the establishment of a full valuation allowance against the benefit of domestic losses or in 2004 due to the expected utilization of prior period net operating losses to offset domestic taxable income in those periods.

Net Income (Loss)

We generated a net loss of \$510,000 in 2005 compared to a net income of \$152,000 in 2004. Our net loss per basic and diluted common share was \$0.02 in 2005 compared to net income per basic and diluted common share of \$0.01 in 2004. The net loss in 2005 and the net income in 2004 resulted primarily from the various factors discussed above. See Note 2, Summary of Significant Accounting Policies, in the Notes to Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K, for the calculation of earnings per share.

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

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

	<u>2004</u>	<u>% of Revenue</u>	<u>2003</u>	<u>% of Revenue</u>	<u>Period over Period Increase (Decrease)</u>
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	<u>\$11,524,000</u>	<u>60.9%</u>	<u>\$11,221,000</u>	<u>63.5%</u>	<u>\$ 303,000</u>

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.

Liquidity and Capital Resources

At December 31, 2005, our working capital was \$20,036,000 compared to \$22,993,000 at December 31, 2004 and \$24,334,000 at December 31, 2003. Cash and cash equivalents totaled \$11,480,000 at December 31, 2005, \$7,493,000 at December 31, 2004, \$2,865,000 at December 31, 2003. Short-term marketable securities were \$122,000 at December 31, 2005, \$4,650,000 at December 31, 2004 and \$12,600,000 at December 31, 2003. We only invest in select money market instruments, municipal securities and corporate issuers. It is our intent to maintain a liquid portfolio to take advantage of investment opportunities. Although our holdings were not significant at December 31, 2005, our short-term marketable securities are primarily invested 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. Also included in marketable securities at December 31, 2005 is \$122,000 in Italian bank bonds held by our Italian subsidiary that are used to support guarantees provided by us. 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.

Net cash flows of \$1,523,000 were provided by operating activities during 2005, compared to \$22,000 that was provided by operating activities in 2004 and \$530,000 that was provided in 2003. Cash provided by operating activities during 2005 was primarily attributable to \$15,000 from the combination of net loss and the non-cash items of depreciation and amortization, the deferred income tax provision, the provision for losses on accounts receivable, and compensation expense relating to our cancellation of stock options pursuant to our July 2005 program, as well as to \$1,327,000 from cash provided from a net working capital decrease, excluding the change in cash balance. This decrease in net working capital was principally due to the May 12, 2005 collection of Italian accounts receivable, partially offset by the resulting required value-added tax payment and increases in inventories, primarily for components necessary for the future production of the PARSEC™ System. Cash provided by operating activities during 2004 was primarily the result of \$1,256,000 from the combination of net income and the non-cash items of depreciation and amortization, provision for losses on accounts receivable, and income tax benefit, offset by \$1,355,000 from cash used to increase net working capital, excluding the change in cash balance. 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 by operating activities during 2003 was principally the result of \$959,000 from the combination of net loss and the non-cash items of depreciation and amortization, provisions for income taxes and for losses on accounts receivable, and stock option compensation expense, partially offset by \$460,000 from cash used to increase net working capital, excluding the change in cash. This increase in net working capital was primarily the result of an increase in accounts receivable and other current assets.

Net cash of \$3,467,000 was provided by investing activities during 2005, compared to \$7,218,000 that was provided during 2004 and \$13,698,000 that was used during 2003. The decrease in cash provided by investing activities in 2005 compared to 2004 and the increase in cash provided by investing activities in 2004 compared to 2003 was primarily the result of our net investments in marketable securities. Additionally, we paid approximately \$278,000 during 2005 as the result of a license agreement we entered into in September 2004 with an Italian diagnostics company to obtain a perpetual, worldwide, royalty-free license of product technology presently used by the Italian diagnostics company to manufacture hepatitis products currently sold by them. In exchange, we agreed to pay four milestone payments totaling 1,000,000 Euro upon the Italian diagnostics company's achievement of certain enumerated performance objectives. The payment of the approximately \$278,000 was the first of these milestone payments. As a result of the satisfaction of the first milestone, we determined that payment of the three remaining milestone payments was probable and, consequently, an accrued license payable of \$948,000 is recorded in the accompanying consolidated balance sheet as of December 31, 2005. The three remaining milestone payments relate to two remaining performance objectives that the Italian diagnostics company is working to achieve on or prior to October 31, 2006 and one remaining performance objective that the Italian diagnostics company is working to achieve on or prior to March 31, 2007. Among other events and actions included in these future milestones are requirements that training be provided to us. This training has been, and will continue to be, expensed as incurred and a corresponding amount will be recognized as a reduction to the product license recorded in the accompanying consolidated balance sheet. While we determined that our payment of the three remaining milestone payments was probable and believe that capitalization as a recoverable asset is appropriate, there remains a risk that we will not be able to obtain product technology that would enable us to manufacture our own hepatitis products or, if we obtain such product technology, that we will not be able to manufacture our own hepatitis products.

Net cash of \$992,000 was used in financing activities during 2005, compared to the \$2,579,000 that was used by financing activities during 2004 and the \$266,000 that was provided by financing activities in 2003. In 2005 we used \$1,608,000 for the cancellation of options to purchase shares of our common stock, which were granted under our 1999 Stock Option Plan, in connection with the July 2005 program we offered to each holder of such options. Pursuant to this program, we offered each holder of options to purchase shares of our common stock, which were granted under our 1999 Stock Option Plan, the opportunity to participate in a program whereby we would cancel 50% of such option holder's options in exchange for a cash payment to such holder of \$3.52 per share (except for the options of Giorgio D'Urso, our Chief Executive Officer and President, for which he would receive a cash payment of \$3.02 per share), such option holder would then exercise all of his or her remaining options by paying to us the exercise price, and such option holder would agree to hold all of the shares of our common stock received upon exercise for a period of at least one year. On July 22, 2005, pursuant to our offer of this program, we entered into agreements with employees and a consultant of our Company and our subsidiaries, including, without limitation, our three executive officers. The participating option holders held a total of 998,795 options, all of which were fully vested, had an exercise price of \$0.73 per share and had an expiration date in the second (and, in one case, the third) quarter of 2006. Pursuant to these agreements, during the third quarter of 2005, we cancelled 499,398 options in exchange for a total payment of \$1,608,000 to the participating option holders, \$1,071,000 of which was recognized as a reduction of capital in excess of par and \$537,000 of which was recognized in operating expenses. Additionally, as part of the total of \$788,000 that was provided in 2005 as a result of the exercise of 683,397 options granted under our stock option plans, we received approximately \$365,000 pursuant to such agreements from the participating option holders who exercised the remaining 499,397 options by paying the option exercise price of \$0.73 per share and who, pursuant to such agreements, agreed to hold all of the shares of our common stock received upon exercise for a period of at least one year. The remaining \$423,000 of the total of \$788,000 that was received from the exercise of stock options during 2005 was provided as a result of the exercise of options granted under our other stock option plans, compared to \$50,000 received in 2004 and \$266,000 received in 2003 from the exercise of stock options. Other financing activities during 2005 included the use of \$173,000 to purchase and redeem 50,000 shares of our common stock from an unaffiliated stockholder as part of the common stock repurchase program approved by our Board of Directors in May 2002, which shares have been retired and resumed the status of authorized and unissued shares. Cash used for financing activities during 2004 included our use of \$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 were retired and also resumed the status of authorized and unissued shares.

Our product research and development expenditures are expected to be approximately \$2,000,000 during 2006. 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 \$1,400,000 will be required in fiscal 2006 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 for the license to us of product technology useful for our own manufacture of hepatitis products. This estimate does not include, however, expenditures relating to our previously reported plans to continue our search to relocate to a new location for our corporate headquarters and the operations of Diamedix. There can be no assurance that we will be successful in our plans to expand or relocate our operations.

Our principal source of short term liquidity is existing cash and cash equivalents and marketable securities, 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 an allowance for doubtful accounts for estimated losses resulting from the inability of our customers to make required or timely payments. On May 12, 2005, we received a payment of approximately 2,000,000 Euro from a governmental region in Italy in satisfaction of previously outstanding accounts receivable balances from hospitals located in the region. A significant portion of this payment related to accounts receivable against which we had previously established allowances. As a result of this collection of receivables, we reduced our allowance for doubtful accounts in our first quarter 2005 financial statements. 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.

Contractual Obligations. The following table summarizes our significant contractual obligations as of December 31, 2005, and the effect such obligations are expected to have on our liquidity and cash flows in future periods.

	Total	Payments due by period			
		Less than 1 Year	1-3 Years	4-5 Years	More than 5 Years
Operating lease obligations	\$2,315,000	\$458,000	\$775,000	\$709,000	\$373,000
Other long-term obligations	680,000	—	68,000	68,000	544,000
Total contractual cash obligations	<u>\$2,995,000</u>	<u>\$458,000</u>	<u>\$843,000</u>	<u>\$777,000</u>	<u>\$917,000</u>

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, 2005, 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, which remains our property, 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 an allowance for doubtful accounts 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 allowance for doubtful accounts was \$974,000 and \$3,081,000 at December 31, 2005 and 2004, respectively. The allowance for doubtful accounts at December 31, 2005 reflects the effect of the bad debt recovery of doubtful accounts receivable of \$1,833,000, primarily due to the recovery of \$1,690,000 recorded in the first quarter of 2005 as discussed 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. Provisions for losses on accounts receivable totaled \$20,000 in 2004 and \$141,000 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 and could adversely affect our operating results. Inventory reserves were \$332,000 and \$436,000 as of December 31, 2005 and 2004, respectively. During 2005, \$301,000 was charged to cost and expenses while \$143,000 was charged in 2004 and \$291,000 was charged in 2003. Included within our inventory balance at December 31, 2005 was approximately \$1,013,000 in PARSEC™ instrumentation and instrument components in anticipation of our pending full commercial product launch.

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 a full valuation allowance of \$4,049,000 against domestic deferred tax assets. Additionally, in 2005 we have recorded a full valuation allowance of \$628,000 against our foreign deferred tax asset as a result of recent losses generated in Italy. Over time we may reach levels of profitability that could cause our management to conclude that it is more likely than not that we will realize all or a portion of our net operating loss carryforwards. Upon reaching such a conclusion, and upon such time as we reversed the entire valuation allowance against the deferred tax asset, we would then provide for income taxes at a rate equal to our effective tax rate.

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

During May 2005, the Financial Accounting Standards Board, or FASB, issued Statement of Financial Accounting Standards, or SFAS, No. 154, *Accounting Changes and Error Corrections*, which replaces Accounting Principles Board, or APB, Opinion No. 20, *Accounting Changes*, and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*, and changes the requirements for the accounting for and reporting of a change in accounting principles for all voluntary changes in accounting principles and to changes required by accounting pronouncements in the unusual instance that the pronouncements do not include specific transition provisions. This Statement requires retrospective application to prior periods' financial statements of changes in accounting principles, unless it is impracticable to determine the period specific effects or cumulative effect of the change. When it is impracticable to determine the period specific effects of an accounting change on one or more individual prior periods presented, this Statement requires that the new accounting principle be applied to the balances of assets and liabilities as the beginning of the earliest period for which retrospective application is practicable and a corresponding adjustment is to be made to the opening balance of retained earnings for that period. When it is impracticable to determine the cumulative effect of applying a change in accounting principle to all prior periods, it requires that the new accounting principle be applied as if it were adopted prospectively from the earliest date practicable. This Statement defines "retrospective application" as the application of a different accounting principle to prior accounting periods as if that principle had always been used or as the adjustment of previously issued financial statements to reflect a change in the reporting entity. It also redefines "restatement" as the revising of previously issued financial statements to reflect the correction of an error. This Statement also requires that a change in depreciation, amortization, or depletion method for long-lived, nonfinancial assets be accounted for as a change in accounting estimate effected by a change in accounting principle. It is effective for fiscal years beginning after December 15, 2005. The impact of adoption of this Statement is not expected to be significant.

During December, 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 discontinued. 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. Effective April 21, 2005, the Securities and Exchange Commission issued an Amendment to Rule 4-01(a) of Regulation S-X regarding the compliance date for SFAS No. 123(R). Under the amendment, registrants are required to file financial statements that comply with SFAS No. 123(R) the first quarter of the first fiscal year beginning after June 15, 2005. We intend to comply with SFAS No. 123(R) effective January 1, 2006. We estimate that the impact of adopting the modified prospective method of SFAS 123(R) will increase compensation expense by approximately \$120,000, \$80,000 and \$30,000 in the years ending December 31, 2006, 2007 and 2008, respectively (excluding the impact of forfeitures and assuming no new share-based payments are granted in the future).

During November, 2004, the FASB issued SFAS No. 151, *Inventory Costs*, an amendment of Accounting Research Bulletin, or 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.

Currency Fluctuations

For the years ended December 31, 2005, December 31, 2004 and December 31, 2003, approximately 34.7%, 36.0% and 33.8%, 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 increases of approximately \$4,000 in net revenues in 2005 compared to 2004 and \$591,000 in net revenues in 2004 compared to 2003. During the three years ended December 31, 2005, no subsidiary was domiciled in a highly inflationary environment and the impact of inflation and changing prices on our net sales and revenues and on income from continuing operations was not material.

Delta represented 34.7% of our net revenues in 2005. 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.

Income Taxes

We recognized an income tax provision (benefit) of \$1,077,000, \$(19,000) and \$80,000 for the years ended December 31, 2005, 2004 and 2003, 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 provision for the year ended December 31, 2005 was different from the amount computed on the income before income taxes at the statutory rate of 35% primarily due to an increase in the valuation allowance, including the creation of a foreign valuation allowance in the year ended December 31, 2005 to fully reserve the remaining foreign deferred tax asset due to the recent losses by our Italian operation. The 2005 current income tax was the result of Italian local income taxes based upon applicable statutory rates effective in Italy.

As of December 31, 2005, 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. At December 31, 2005, we also had no net foreign deferred tax asset due to the creation of a foreign valuation allowance in the three months ended March 31, 2005 to fully reserve the remaining foreign deferred tax asset due to recent losses by our Italian operation. 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. Upon such time as we reverse the entire valuation allowance against the deferred tax asset, we would then provide for income taxes at a rate equal to our effective tax rate.

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**

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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, 2005 and 2004, and the related consolidated statements of operations, shareholders' equity and cash flows for each of the three years in the period ended December 31, 2005. Our audits also included the financial statement schedule listed in the Index at Item 15(a). 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, 2005 and 2004, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2005, 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
March 13, 2006

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

**CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2005 AND 2004**

	<u>2005</u>	<u>2004</u>
<u>ASSETS</u>		
CURRENT ASSETS:		
Cash and cash equivalents	\$11,479,568	\$ 7,492,885
Marketable securities	122,045	4,650,000
Accounts receivable, net of allowances for doubtful accounts of \$973,855 and \$3,080,952, respectively	6,695,353	7,739,548
Inventories, net	5,608,584	5,143,611
Deferred income taxes	—	1,060,439
Other current assets	1,164,890	1,143,034
Total current assets	<u>25,070,440</u>	<u>27,229,517</u>
PROPERTY, PLANT AND EQUIPMENT:		
Land	352,957	352,957
Buildings and improvements	2,711,785	2,575,222
Machinery and equipment	2,968,885	2,942,140
Furniture and fixtures	1,397,936	1,424,347
	<u>7,431,563</u>	<u>7,294,666</u>
Less—Accumulated depreciation	<u>(5,217,982)</u>	<u>(5,035,848)</u>
	<u>2,213,581</u>	<u>2,258,818</u>
OTHER ASSETS:		
Goodwill, net	6,722,725	6,632,986
Equipment on lease, net	585,295	719,277
Product license	1,255,936	—
Other	55,553	73,627
	<u>8,619,509</u>	<u>7,425,890</u>
Total assets	<u>\$35,903,530</u>	<u>\$36,914,225</u>
<u>LIABILITIES AND SHAREHOLDERS' EQUITY</u>		
CURRENT LIABILITIES:		
Accounts payable	\$ 1,190,204	\$ 1,207,042
Accrued license payable	947,920	—
Accrued expenses	2,895,836	3,029,820
Total current liabilities	5,033,960	4,236,862
OTHER LONG-TERM LIABILITIES	680,006	631,391
Total liabilities	<u>5,713,966</u>	<u>4,868,253</u>
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY:		
Common stock, par value \$0.01, authorized 50,000,000 shares, issued and outstanding 27,623,554 in 2005 and 27,019,829 in 2004	276,235	270,198
Additional paid-in capital	40,548,950	41,010,041
Accumulated deficit	(9,458,371)	(8,948,844)
Accumulated other comprehensive loss	<u>(1,177,250)</u>	<u>(285,423)</u>
Total shareholders' equity	30,189,564	32,045,972
Total liabilities and shareholders' equity	<u>\$35,903,530</u>	<u>\$36,914,225</u>

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, 2005, 2004 AND 2003

	<u>2005</u>	<u>2004</u>	<u>2003</u>
NET REVENUE	\$19,761,807	\$18,933,468	\$17,673,478
COST OF SALES	8,092,617	7,724,076	7,484,578
Gross profit	<u>11,669,190</u>	<u>11,209,392</u>	<u>10,188,900</u>
OPERATING EXPENSES:			
Selling	6,107,462	5,811,803	5,335,702
General and administrative	3,518,926	4,378,915	4,587,870
Research and development	1,765,998	1,333,079	1,296,734
Total operating expenses	<u>11,392,386</u>	<u>11,523,797</u>	<u>11,220,306</u>
Income (loss) from operations	<u>276,804</u>	<u>(314,405)</u>	<u>(1,031,406)</u>
OTHER INCOME, NET:			
Interest income	352,304	223,230	225,556
Other income (expense), net	(62,048)	224,775	210,936
Total other income, net	<u>290,256</u>	<u>448,005</u>	<u>436,492</u>
Income (loss) before income taxes	567,060	133,600	(594,914)
INCOME TAX PROVISION (BENEFIT)	1,076,587	(18,660)	79,781
Net income (loss)	<u>\$ (509,527)</u>	<u>\$ 152,260</u>	<u>\$ (674,695)</u>
Basic earnings (loss) per common share	<u>\$ (.02)</u>	<u>\$.01</u>	<u>\$ (.02)</u>
Diluted earnings (loss) per common share	<u>\$ (.02)</u>	<u>\$.01</u>	<u>\$ (.02)</u>
WEIGHTED AVERAGE SHARES OUTSTANDING:			
Basic	<u>27,295,176</u>	<u>27,341,043</u>	<u>27,589,908</u>
Diluted	<u>27,295,176</u>	<u>28,542,970</u>	<u>27,589,908</u>

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, 2005, 2004 AND 2003

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Loss	Total Shareholders' Equity
	Shares	Amount				
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
Comprehensive loss:						
Net loss	—	—	—	(509,527)	—	(509,527)
Translation adjustment	—	—	—	—	(891,827)	(891,827)
Comprehensive loss						(1,401,354)
Repurchase of common stock	(50,000)	(500)	(172,000)	—	—	(172,500)
Exercise of stock options	653,725	6,537	782,118	—	—	788,654
Cancellation of stock options	—	—	(1,071,209)	—	—	(1,071,208)
BALANCE, December 31, 2005	<u>27,623,554</u>	<u>\$276,235</u>	<u>\$40,548,950</u>	<u>\$(9,458,371)</u>	<u>\$(1,177,250)</u>	<u>\$30,189,564</u>

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, 2005, 2004 AND 2003

	<u>2005</u>	<u>2004</u>	<u>2003</u>
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net income (loss)	\$ (509,527)	\$ 152,260	\$ (674,695)
Adjustments to reconcile net income (loss) to net cash provided by operating activities—			
Depreciation and amortization	828,455	1,183,028	1,111,080
(Recovery of) provision for doubtful accounts receivable	(1,832,911)	20,063	140,528
Compensation expense relating to stock option cancellation	536,672	—	—
Stock option compensation expense	—	—	222,225
Deferred income tax provision (benefit)	992,564	(99,521)	160,071
Changes in operating assets and liabilities:			
Accounts receivable	2,166,743	(661,257)	(315,190)
Inventories	(776,745)	(509,665)	83,419
Other current assets	(161,353)	(307,431)	(143,604)
Other assets	46,961	6,816	6,962
Accounts payable and accrued expenses	98,566	123,213	(84,553)
Other long-term liabilities	133,207	114,967	24,204
Net cash provided by operating activities	<u>1,522,632</u>	<u>22,473</u>	<u>530,447</u>
CASH FLOWS FROM INVESTING ACTIVITIES:			
Capital expenditures, net	(350,597)	(406,787)	(381,008)
Acquisition of equipment on lease	(432,462)	(325,448)	(716,963)
Acquisition of product license	(277,717)	—	—
Purchases of marketable securities	(14,603,587)	(1,750,000)	(15,300,000)
Proceeds from sales of marketable securities	19,131,543	9,700,000	2,700,000
Net cash provided by (used in) investing activities	<u>3,467,180</u>	<u>7,217,765</u>	<u>(13,697,971)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from stock option exercises	788,654	49,800	265,970
Cancellation of stock options	(1,607,880)	—	—
Repurchase of common stock	(172,500)	(2,628,500)	—
Net cash (used in) provided by financing activities	<u>(991,726)</u>	<u>(2,578,700)</u>	<u>265,970</u>
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS ..	<u>(11,403)</u>	<u>(33,492)</u>	<u>(175,270)</u>
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	3,986,683	4,628,046	(13,076,824)
CASH AND CASH EQUIVALENTS, beginning of year	<u>7,492,885</u>	<u>2,864,839</u>	<u>15,941,663</u>
CASH AND CASH EQUIVALENTS, end of year	<u>\$ 11,479,568</u>	<u>\$ 7,492,885</u>	<u>\$ 2,864,839</u>
SUPPLEMENTAL DISCLOSURES:			
Interest paid	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>
Income taxes paid	<u>\$ —</u>	<u>\$ 318,686</u>	<u>\$ —</u>
NONCASH INVESTING ACTIVITY:			
Acquisition of product license	<u>\$ 1,030,000</u>	<u>\$ —</u>	<u>\$ —</u>

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.

On July 25, 2005, IVAX Corporation ("IVAX"), the Company's approximately 72.4% stockholder, entered into a definitive Agreement and Plan of Merger with Teva Pharmaceutical Industries Limited ("Teva"), providing for IVAX to be merged into a wholly-owned subsidiary of Teva. On January 26, 2006, the merger was consummated and IVAX became a wholly-owned subsidiary of Teva for an aggregate purchase price of approximately \$3.8 billion in cash and 123 million Teva ADRs. The transaction was reported to be valued, for accounting purposes, at \$7.9 billion, based on the value of the Teva ADRs during the five trading day period commencing two trading days before the date of the definitive Agreement and Plan of Merger. As a result of the merger, Teva now, indirectly through its IVAX subsidiary, owns approximately 72.4% of the outstanding shares of the Company's common stock.

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

During May 2005, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 154, *Accounting Changes and Error Corrections*, which replaces Accounting Principles Board ("APB") Opinion No. 20, *Accounting Changes*, and SFAS No. 3, *Reporting Accounting Changes in Interim Financial Statements*, and changes the requirements for the accounting for and reporting of a change in accounting principles for all voluntary changes in accounting principles and to changes required by accounting pronouncements in the unusual instance that the pronouncements do not include specific transition provisions. This Statement requires retrospective application to prior periods' financial statements of changes in accounting principles, unless it is impracticable to determine the period specific effects or cumulative effect of the change. When it is impracticable to determine the period specific effects of an accounting change on one or more individual prior periods presented, this Statement requires that the new accounting principle be applied to the balances of assets and liabilities as the beginning of the earliest period for which retrospective application is practicable and a corresponding adjustment is to be made to the opening balance of retained earnings for that period. When it is

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

impracticable to determine the cumulative effect of applying a change in accounting principle to all prior periods, it requires that the new accounting principle be applied as if it were adopted prospectively from the earliest date practicable. This Statement defines “retrospective application” as the application of a different accounting principle to prior accounting periods as if that principle had always been used or as the adjustment of previously issued financial statements to reflect a change in the reporting entity. It also redefines “restatement” as the revising of previously issued financial statements to reflect the correction of an error. This Statement also requires that a change in depreciation, amortization, or depletion method for long-lived, nonfinancial assets be accounted for as a change in accounting estimate effected by a change in accounting principle. It is effective for fiscal years beginning after December 15, 2005. The impact of adoption of this Statement is not expected to be significant.

During December, 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 discontinued. 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. Effective April 21, 2005, the Securities and Exchange Commission issued an Amendment to Rule 4-01(a) of Regulation S-X regarding the compliance date for SFAS No. 123(R). Under the amendment, registrants are required to file financial statements that comply with SFAS No. 123(R) the first quarter of the first fiscal year beginning after June 15, 2005. The Company intends to comply with SFAS No. 123(R) effective January 1, 2006. The Company estimates that the impact of adopting the modified prospective method of SFAS 123(R) will increase compensation expense by approximately \$120,000, \$80,000 and \$30,000 in the years ending December 31, 2006, 2007 and 2008, respectively (excluding the impact of forfeitures and assuming no new share-based payments are granted in the future).

During November, 2004, the FASB issued SFAS No. 151, *Inventory Costs*, an amendment of Accounting Research Bulletin (“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.

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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

The Company only invests in select money market instruments, municipal securities and corporate issuers. It is our intent to maintain a liquid portfolio to take advantage of investment opportunities. In the years ended December 31, 2005 and 2004, available cash was typically invested in 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 primarily consisted of taxable municipal bonds and government agency securities and were deemed short-term, classified as available for sale securities and recorded at cost which approximated 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, 2005, 2004 and 2003, realized gains and losses were not material. Included in marketable securities at December 31, 2005 is \$122,045 in Italian bank bonds held by the Company's Italian subsidiary that are used to support guarantees provided by the Company.

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.

On May 12, 2005, the Company received a payment of approximately 2,000,000 Euro from a governmental region in Italy in satisfaction of previously outstanding accounts receivable balances from hospitals located in the region. A significant portion of this payment related to accounts receivable against which the Company had previously established allowances. In order to recognize the impact of the collection of these receivables, the Company reduced its allowance for doubtful accounts and recognized a corresponding bad debt recovery of \$1,690,000 that is included as a reduction of general and administrative expenses in the accompanying consolidated statement of operations for the year ended December 31, 2005.

The allowance for doubtful accounts was \$973,855, \$3,080,952 and \$2,897,833 at December 31, 2005, December 31, 2004 and December 31, 2003, respectively, and activity for the years then ended was as follows:

	<u>2005</u>	<u>2004</u>	<u>2003</u>
January 1 balance	\$ 3,080,952	\$2,897,833	\$2,392,553
(Recovery) provision	(1,832,911)	20,063	140,528
Write-offs	(17,577)	(30,104)	(58,830)
Effects of changes in foreign exchange rates	(256,609)	193,160	423,582
Balance at December 31	<u>\$ 973,855</u>	<u>\$3,080,952</u>	<u>\$2,897,833</u>

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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,	
	2005	2004
Raw materials	\$1,472,994	\$1,631,079
Work-in-process	1,223,572	737,282
Finished goods	2,912,018	2,775,250
Total	\$5,608,584	\$5,143,611

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 \$306,011, \$326,270 and \$312,662 for the years ended December 31, 2005, 2004 and 2003, 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,	
	2005	2004
Equipment on lease at cost	\$5,556,232	\$5,911,341
Less—Accumulated amortization	4,970,937	5,192,064
	\$ 585,295	\$ 719,277

Equipment on lease is amortized over three years. Amortization expense related to equipment on lease was \$514,110, \$848,427 and \$790,085 for the years ended December 31, 2005, 2004 and 2003, respectively.

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Long Lived Assets Including Goodwill

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

	December 31,	
	2005	2004
Goodwill	\$9,139,755	\$9,083,666
Less—Accumulated amortization	2,417,030	2,450,680
	\$6,722,725	\$6,632,986

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

	Balance 2005	Foreign Exchange	Balance 2004
Domestic	\$2,050,290	\$ —	\$2,050,290
Italian	4,672,435	89,739	4,582,696
Consolidated goodwill	\$6,722,725	\$89,739	\$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, 2005 and no impairments were noted.

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 net 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.

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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. Provisions and discounts for the years ended December 31, 2005, 2004 and 2003 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, which remains the property of the Company, is utilized by customers to expedite the performance of certain tests and its use is paid for over an agreed upon contract period, typically three to five years, by the purchase of test kits. Revenue is recognized ratably over the rental period. Upon completion of the contract period, the instrument is returned to the Company.

Provisions for estimated warranty claims are established by the Company concurrently with the recognition of revenue. Provisions are established in accordance with United States 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 as incurred.

Stock-Based Compensation Plans

The Company’s pro forma net income (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. 148, *Accounting for Stock Based Compensation—Transition and Disclosure*, and SFAS No. 123, *Stock-Based Compensation*, using the Black-Scholes option pricing model, are indicated below for the years ended December 31, 2005, 2004 and 2003.

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net income (loss) as reported ⁽¹⁾	\$ (509,527)	\$ 152,260	\$ (674,695)
Add: Compensation expense from stock option cancellation	536,672	—	—
Deduct: Total stock-based employee compensation expense determined under fair value based method for all awards	<u>(591,971)</u>	<u>(989,291)</u>	<u>(287,111)</u>
Pro forma net loss	<u>\$ (564,826)</u>	<u>\$ (837,031)</u>	<u>\$ (961,806)</u>
Pro forma basic and diluted loss per share	<u>\$ (0.02)</u>	<u>\$ (0.03)</u>	<u>\$ (0.03)</u>
Pro forma weighted average fair value of options granted	<u>\$ 2.90</u>	<u>\$ 4.48</u>	<u>\$ 4.24</u>
Assumptions:			
Expected life (years)	2.8	3.0	5.0
Risk-free interest rate	3.8%	3.5%	3.5%
Expected volatility	71%	74%	99%
Dividend yield	—	—	—

(1) Includes stock-based employee compensation cost of \$222,225 for the year ended December 31, 2003, 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.

Valuations are based on highly subjective assumptions about the future, including stock price volatility and exercise patterns. During the fourth quarter of 2005, it was determined that options granted in 2004 and that vested immediately were not fully expensed in the year ended December 31, 2004. Accordingly, the 2004 deduction for stock based compensation expense determined under the fair value method for 2004 was increased by \$646,858, or a pro forma basic and diluted loss per share effect of \$0.02.

Comprehensive Income (Loss)

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

	<u>Year Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Net income (loss)	\$ (509,527)	\$ 152,260	\$ (674,695)
Foreign currency translations adjustment	(891,827)	509,130	754,250
Comprehensive income (loss)	<u>\$(1,401,354)</u>	<u>\$661,390</u>	<u>\$ 79,555</u>

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, 2005 is as follows:

	<u>December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Basic weighted average shares outstanding	27,295,176	27,341,043	27,589,908
Effect of diluted securities—			
Stock options and warrants	—	1,201,927	—
Diluted weighted average shares outstanding	<u>27,295,176</u>	<u>28,542,970</u>	<u>27,589,908</u>
Not included in the calculation of diluted earnings (loss) per share because their impact is antidilutive:			
Stock options and warrants outstanding	<u>922,532</u>	<u>793,815</u>	<u>2,317,628</u>

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

Reclassifications

Certain reclassifications have been made to prior years consolidated financial statements to conform to the current year presentation.

3 MERGER AND ACQUISITION

On March 14, 2001, b2bstores.com Inc. ("b2bstores.com"), 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." 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.

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 9, *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 was recorded in general and administrative expense in the accompanying consolidated statements of operations for the year ended December 31, 2003.

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, 2005 and 2004, \$4,633,747 and \$5,834,665, respectively, of total net accounts receivable were due in Italy. At December 31, 2005 and 2004, 57.0% and 64.8% of total net accounts receivable were due from hospitals and laboratories controlled by the Italian government.

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.

5 PRODUCT LICENSE

In September 2004, the Company entered into a license agreement with an Italian diagnostics company to obtain a perpetual, worldwide, royalty-free license of product technology presently used by the Italian diagnostics company to manufacture hepatitis products currently sold by them. In exchange, the Company agreed to pay four milestone payments totaling 1,000,000 Euro upon the Italian diagnostics company's achievement of certain enumerated performance objectives. In March 2005, the Company paid the first of these milestone payments, in the amount of \$277,717. As a result of the satisfaction of the first milestone, the Company determined that payment of the three remaining milestone payments was probable and, consequently, an accrued license payable for the remaining 800,000 Euro was recorded during the first quarter of 2005. The outstanding balance of this accrued license payable was \$947,920 in the accompanying consolidated balance sheet as of

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

December 31, 2005. The three remaining milestone payments relate to two remaining performance objectives that the Italian diagnostics company is working to achieve on or prior to October 31, 2006 and one remaining performance objective that the Italian diagnostics company is working to achieve on or prior to March 31, 2007. Among the other events and actions included in these future milestones are requirements that training be provided to the Company. This training will be expensed as incurred, and a corresponding amount will be recognized as a reduction to the product license recorded in the accompanying consolidated balance sheet. Training expenses of \$35,064 were incurred during 2005.

6 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. The Company has established a full valuation allowance on its net domestic deferred tax assets, which are primarily comprised of net operating loss carryforwards. As of December 31, 2005 and 2004, the Company 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. Additionally, as of December 31, 2005, the Company had no net foreign deferred tax asset, as a full valuation allowance was provided during the first quarter of 2005 as a result of recent losses by the Company's Italian operation. As of December 31, 2004, foreign deferred assets of \$1,060,439 were included in other current assets. This amount included the tax effect of the reduction in the accounts receivable allowance recognized as a result of the May 12, 2005 collection of certain previously reserved Italian accounts receivable discussed in Note 2, *Summary of Significant Accounting Policies*, above. The remainder was eliminated due to the Company's establishment of the full valuation allowance on its net foreign tax asset. Subsequent revisions to the estimated net realizable value of the deferred tax asset could cause the provision for income taxes to vary significantly from period to period.

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

	<u>Year Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
Current:			
Foreign	\$ 84,023	\$ 80,861	\$(80,290)
Deferred:			
Foreign	992,564	(99,521)	160,071
Total	<u>\$1,076,587</u>	<u>\$(18,660)</u>	<u>\$ 79,781</u>

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

	<u>Year Ended December 31,</u>		
	<u>2005</u>	<u>2004</u>	<u>2003</u>
United States	\$(59,636)	\$ 297,352	\$(576,166)
Foreign	626,696	(163,752)	(18,748)
Total	<u>\$567,060</u>	<u>\$ 133,600</u>	<u>\$(594,914)</u>

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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

	December 31,	
	2005	2004
Current:		
Accounts receivable allowances	\$ 332,561	\$ 1,087,918
Reserves and accruals	435,190	409,333
Capitalized inventory costs	142,444	131,969
Foreign net operating losses	—	108,432
Valuation allowance	(910,195)	(677,213)
Deferred income taxes	—	1,060,439
Long-Term:		
Depreciation and basis differences on fixed assets	(197,431)	(202,572)
Other	5,925	6,777
Foreign net operating losses	407,520	—
Domestic net operating losses	3,550,170	2,671,500
Valuation allowance	(3,766,184)	(2,468,928)
Amount included in "Other assets"	—	6,777
Net deferred tax asset	\$ —	\$ 1,067,216

A reconciliation of the difference between the expected provision (benefit) for income taxes using the statutory U.S. Federal tax rate and the Company's actual provision (benefit) is as follows:

	Year Ended December 31,		
	2005	2004	2003
Provision (benefit) for income taxes at U.S. Federal statutory rate of 35%	\$ 198,471	\$ 46,760	\$(206,942)
Change in valuation allowance (excluding portion relating to stock options)	706,529	(104,073)	196,859
Foreign tax rate differential and global permanent differences	171,587	38,653	89,864
Provision (benefit) for income taxes	\$1,076,587	\$ (18,660)	\$ 79,781

The Company's income tax provision or benefit for the years ended December 31, 2005, 2004 and 2003 was different from the amount computed on the loss before provision (benefit) for income taxes at the statutory rate of 35% primarily due to the change in the valuation allowance, including the creation of a full foreign valuation allowance in the year ended December 31, 2005 and foreign tax rate differential and global permanent differences. Domestic losses include non-deductible stock option compensation expense of \$222,225 in the year ended December 31, 2003.

As discussed above, the Company has established a full valuation allowance on its net domestic deferred tax assets, which are primarily comprised of net operating loss carryforwards and in 2005 provided a full valuation allowance on the foreign net deferred income tax assets. During the years ended December 31, 2005, 2004 and 2003, the Company increased its valuation allowance by approximately \$1,530,000, \$62,000 and \$346,000, respectively. Net operating losses generated by the Company after March 14, 2001 total \$9,103,000, of which \$4,010,000 are available for use prior to their expiration in 2021. Additionally, net operating losses of \$1,595,000, \$350,000, \$710,000 and \$2,438,000 are available for use prior to their expirations

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

in 2022, 2023, 2024 and 2025, respectively. Approximately \$3,700,000 of the domestic net operating loss at December 31, 2005, representing approximately \$1,300,000 (including approximately \$800,000, \$100,000 and \$100,000 for the three years ended December 31, 2005, 2004 and 2003, respectively) 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.

The Company's net operating loss carryforwards may be limited in the future as a result of the acquisition of IVAX by Teva.

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.

7 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 \$67,000, \$68,000 and \$69,000 were made into this plan during the years ended December 31, 2005, 2004 and 2003, respectively.

8 ACCRUED EXPENSES

Accrued expenses consist of the following:

	December 31,	
	2005	2004
Payroll costs	\$ 876,926	\$ 723,417
Taxes	1,319,777	1,700,861
Professional fees	267,351	316,942
Royalties	76,264	73,509
Other	355,518	215,091
	\$2,895,836	\$3,029,820

9 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. During 2005, the Company purchased and redeemed a total of 50,000 shares of the Company's common stock at

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

a price of \$3.45 per share in accordance with the terms of this repurchase program. These shares have been retired and have resumed the status of authorized and unissued shares. There were no share repurchases under this program during 2003 or 2004. The total number of shares of common stock repurchased by the Company since the inception of its repurchase program is 1,184,573.

During 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 a price of \$4.00 per share under 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 to purchase up to 400,000 shares of the Company's common stock at a price of \$13.20 per share. These warrants expired unexercised in February 2005.

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, 2005, no options were outstanding to 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, 2005, 8,333 options granted at an exercise price of \$2.56 per share under the Performance Plan prior to the Merger remained outstanding following the exercise of 181,500 options and termination of 118,500 options during the year ended December 31, 2005. During the year ended December 31, 2004, there were no exercises or terminations of options granted under the Performance Plan prior to the Merger. During the year ended December 31, 2003, 100,000 options granted prior to the consummation of the Merger were exercised and there were no terminations. 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, 2005, 175,000 options at an exercise price of \$6.40 were outstanding from this grant. All remaining outstanding options granted by b2bstores.com prior to the Merger will expire in March 2006.

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

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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 year ended December 31, 2003, 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, following the exercise of 39,000 options and termination of 2,000 options in 2003, and no option activity in 2004, 1,016,795 options to purchase shares of common stock were outstanding under the 1999 Plan. During the year ended December 31, 2005, the Company offered each holder of these 1,016,795 options granted under the 1999 Plan the opportunity to participate in a program whereby the Company would cancel 50% of such option holder's options in exchange for a cash payment to such holder of \$3.52 per share (except for the options of Giorgio D'Urso, the Company's Chief Executive Officer and President, for which he would receive a cash payment of \$3.02 per share), such option holder would then exercise all of his or her remaining options by paying to the Company the exercise price, and such option holder would agree to hold all of the shares of the Company's common stock received upon exercise for a period of at least one year. On July 22, 2005, pursuant to the Company's offer of this program, the Company entered into agreements with employees and a consultant of the Company and its subsidiaries, including, without limitation, the three executive officers of the Company. The participating option holders held a total of 998,795 options, all of which options were fully vested, had an exercise price of \$0.73 per share and had an expiration date in the second (and, in one case, the third) quarter of 2006. Pursuant to these agreements, during the third quarter of 2005, the Company cancelled 499,398 options in exchange for a payment to the participating option holders of \$1,607,880, the participating option holders exercised the remaining 499,397 options by paying to the Company the aggregate exercise price of approximately \$365,000, and each participating option holder agreed to hold all of the shares of the Company's common stock received upon exercise for a period of at least one year. The payment of \$1,607,880 to the participating option holders has been recognized as aggregate employment compensation expense of \$536,672 and as a reduction of capital in excess of par of \$1,071,208. As a result of the participation of all but one of the option holders under the 1999 Plan in this program, 18,000 stock options remain outstanding under the 1999 Plan. The Company does not have any current intention of issuing any additional stock options 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, 2005, options for 721,199 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, 2003, 35,000 options to purchase shares of common stock were granted under the Performance Plan while, of the options granted after the consummation of the Merger, 1,250 options were exercised and 8,950 options were terminated. During the year ended December 31, 2004, 205,349 options were granted under the Performance Plan, while, of the options granted after the consummation of the Merger, 17,625 options were exercised and 15,775 options were terminated. Additionally, during the year ended December 31, 2005, 165,000 options were granted under the Performance Plan, while, of the options granted after the consummation of the Merger, 2,500 options were exercised and 30,750 options were terminated.

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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:

	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>
Outstanding at January 1, 2003	1,450,495	\$1.28
Granted	35,000	5.20
Terminated	(10,950)	2.09
Exercised	<u>(40,250)</u>	0.78
Outstanding at December 31, 2003	1,434,295	1.38
Granted	205,349	6.52
Terminated	(15,775)	2.90
Exercised	<u>(17,625)</u>	2.83
Outstanding at December 31, 2004	1,606,244	2.01
Granted	165,000	4.37
Cancellations	(499,398)	0.73
Terminated	(30,750)	3.12
Exercised	<u>(501,897)</u>	0.74
Outstanding at December 31, 2005	<u>739,199</u>	<u>\$4.22</u>
Options exercisable at December 31, 2005	<u>502,012</u>	<u>\$4.51</u>

<u>Range of Exercise Prices</u>	<u>Options Outstanding</u>			<u>Options Exercisable</u>	
	<u>Number Outstanding</u>	<u>Weighted Average Remaining Contractual Life (In Years)</u>	<u>Weighted Average Exercise Price</u>	<u>Number Exercisable</u>	<u>Weighted Average Exercise Price</u>
\$0.73	18,000	0.5	\$0.73	18,000	\$0.73
\$1.35-\$2.40	82,350	3.5	\$2.10	73,050	\$2.06
\$2.88-\$3.00	235,000	2.2	\$2.98	60,000	\$2.93
\$4.35-\$4.91	165,000	9.5	\$4.37	145,000	\$4.37
\$5.20-\$7.12	238,849	5.3	\$6.32	205,962	\$6.26
	<u>739,199</u>			<u>502,012</u>	

10 SEGMENT INFORMATION

The Company's management reviews financial information, allocates resources and manages the business by geographic region. The domestic region, which includes corporate expenditures, contains the Company's subsidiaries in the United States. 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.

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

	<u>Domestic</u>	<u>Italian</u>	<u>Eliminations</u>	<u>Total</u>
December 31, 2005:				
External net sales	\$12,896,731	\$ 6,865,076	\$ —	\$19,761,807
Intercompany sales	1,090,877	340,293	(1,431,170)	—
Net revenue	<u>\$13,987,608</u>	<u>\$ 7,205,369</u>	<u>\$(1,431,170)</u>	<u>\$19,761,807</u>
Income (loss) from operations	<u>\$ (686,480)</u>	<u>\$ 970,885</u>	<u>\$ (7,601)</u>	<u>\$ 276,804</u>
Assets	<u>\$20,235,634</u>	<u>\$15,667,896</u>	<u>\$ —</u>	<u>\$35,903,530</u>
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	<u>\$12,948,236</u>	<u>\$ 7,037,924</u>	<u>\$(1,052,692)</u>	<u>\$18,933,468</u>
Income (loss) from operations	<u>\$ (224,503)</u>	<u>\$ (226,883)</u>	<u>\$ 136,981</u>	<u>\$ (314,405)</u>
Assets	<u>\$20,082,250</u>	<u>\$16,831,975</u>	<u>\$ —</u>	<u>\$36,914,225</u>
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	<u>\$12,979,037</u>	<u>\$ 6,104,071</u>	<u>\$(1,409,630)</u>	<u>\$17,673,478</u>
Loss from operations	<u>\$ (944,319)</u>	<u>\$ (77,026)</u>	<u>\$ (10,061)</u>	<u>\$(1,031,406)</u>
Assets	<u>\$22,844,523</u>	<u>\$15,520,971</u>	<u>\$ —</u>	<u>\$38,365,494</u>

11 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, 2005, 2004 and 2003 totaled \$558,822, \$429,803 and \$403,621, respectively. The future minimum lease payments under non-cancellable capital leases and their related assets recorded at December 31, 2005 and 2004 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, 2005, were as follows:

2006	\$ 457,512
2007	388,366
2008	387,133
2009	348,323
2010	360,763
Thereafter	373,203
Total minimum lease payments	<u>\$2,315,300</u>

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

IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS—(Continued)

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.

12 RELATED PARTY TRANSACTIONS

IVAX continues to provide certain services to the Company under a cost-plus service agreement. No material payments were made during 2005, 2004 or 2003 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 2005, 2004 and 2003, the Company paid \$617,000, \$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, 2005, 2004 and 2003, the Company paid \$60,000, \$82,000 and \$74,000, respectively, in premiums to IVAX for property insurance coverage.

13 QUARTERLY FINANCIAL INFORMATION (UNAUDITED)

The following table summarizes selected quarterly data of the Company for the years ended December 31, 2005 and 2004 (in thousands except per share data):

	<u>First Quarter⁽¹⁾</u>	<u>Second Quarter</u>	<u>Third Quarter⁽²⁾</u>	<u>Fourth Quarter</u>	<u>Full Year</u>
2005					
Net revenue	\$5,383	\$5,244	\$ 4,669	\$4,466	\$19,762
Gross profit	3,246	3,273	2,519	2,631	11,669
Income (loss) from operations	1,876	124	(1,185)	(538)	277
Net income (loss)	838	155	(1,100)	(403)	(510)
Basic and diluted net income (loss) per share	0.03	0.01	(0.04)	(0.01)	(0.02)
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

(1) Includes the effect of the bad debt recovery in 2005 discussed in Note 2, *Summary of Significant Accounting Policies—Accounts Receivable and Allowance for Doubtful Accounts*, and the creation of a full valuation allowance on the Company's foreign net deferred tax assets discussed in Note 6, *Income Taxes*.

(2) Includes the effect of compensation expense recorded in 2005 as a result of the cancellation of stock options discussed in Note 9, *Shareholders' Equity—Stock Option Plans*.

Basic and diluted net income (loss) per share for each of the quarters presented above is based on the respective weighted average number of shares for the quarters. The sum of the quarters may not necessarily be equal to the full year basic and diluted net income (loss) per share amounts due to the effects of rounding.

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

None.

ITEM 9A. 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, 2007, so long as we continue to meet the definition of a non-accelerated filer. In our Annual Report on Form 10-K for the year ending December 31, 2007, 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 relatively 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 and/or material weaknesses.

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 20, 2006.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Giorgio D'Urso	70	Chief Executive Officer, President and Director
Duane M. Steele	55	Vice President—Business Development
Mark S. Deutsch	43	Chief Financial Officer and Vice President—Finance
Phillip Frost, M.D.	69	Chairman of the Board of Directors
Neil Flanzraich	62	Director
Jane H. Hsiao, Ph.D.	58	Director
Fernando L. Fernandez	45	Director
Glenn L. Halpryn	45	Director
John B. Harley, M.D.	56	Director
Jose J. Valdes-Fauli	54	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 20, 2006. 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 70, has served as our President and Chief Executive Officer and as a director since the merger with the pre-merger Diagnostics 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 36 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 55, has served as our Vice President—Business Development since the merger with the pre-merger Diagnostics in 2001 and had served in the same capacity with the pre-merger Diagnostics since 1996. He joined Diamedix in 1995 and has over 28 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 Manager 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 43, has served as Chief Financial Officer and Vice President—Finance since the merger with the pre-merger Diagnostics in 2001 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 12 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.

Dr. Phillip Frost, age 69, has served as Chairman of the Board of Directors since the merger with the pre-merger Diagnostics in 2001. He has served as the Vice Chairman of Teva since January 2006. Since 1987, he has served as the Chief Executive Officer of IVAX. From 1987 until January 2006, he had served as the Chairman of the Board of Directors of IVAX. 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 Corporation (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 62, has served as a director since the merger with the pre-merger Diagnostics in 2001 and had served as a director of the pre-merger Diagnostics since September 1998. Mr. Flanzraich is a private investor. He had served as Vice Chairman and President of IVAX from May 1998 until January 2006, and as a director of IVAX from 1997 until January 2006. 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), Continucare Corporation (healthcare) and Equity One, Inc. (real estate investment trust).

Dr. Jane H. Hsiao, age 58, has served as a director since the merger with the pre-merger Diagnostics in 2001. Prior to January 2006, she had 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. Fernando L. Fernandez, age 45, has served as a director since April 2005. Mr. Fernandez serves as Senior Vice President—Finance, Chief Financial Officer, Treasurer, and Secretary of Continucare Corporation. Mr. Fernandez, a certified public accountant, served as Senior Vice President—Finance, Chief Financial Officer, Treasurer, and Secretary of Whitman Education Group, Inc. from 1996 until 2003. From 1991 to 1996 and for a brief period after his service at Whitman Education Group, Inc., Mr. Fernandez served as Chief Financial Officer

of several private investment entities owned by Phillip Frost, M.D. Prior to 1991, Mr. Fernandez served as Audit Manager for PricewaterhouseCoopers LLP (formerly Coopers & Lybrand) Miami, Florida.

Mr. Glenn L. Halpryn, age 45, 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 and the President of Chelsea Management Corporation since September 2004. 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 56, has served as a director since the merger with the pre-merger Diagnostics in 2001. He has held various positions at the University of Oklahoma Health Sciences Center since 1982. In the Department of Medicine, his positions include Chief of Rheumatology, Allergy and Immunology Section 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 and Treasurer of JK Autoimmunity, Inc.

Mr. Jose J. Valdes-Fauli, age 54, has served as a director since December 2002. Mr. Valdes-Fauli has been the 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 30 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, 2005.

Audit Committee Members and Financial Expert

The members of the Audit Committee of the Board of Directors are Fernando L. Fernandez, Glenn L. Halpryn and Jose J. Valdes-Fauli. The Board of Directors has determined that our Audit Committee has two "audit committee financial experts" as such term is defined in the applicable regulations of the Securities and Exchange Commission. The Board of Directors determined that each of Messrs. Fernandez and Valdes-Fauli has the attributes, education and experience of an "audit committee financial expert" and that each of Messrs. Fernandez and Valdes-Fauli 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.

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 2005, 2004 and 2003 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

Name and Principal Position	Year	Annual Compensation		Long Term Compensation	All Other Compensation (\$)
		Salary (\$)	Bonus (\$)	Shares Underlying Stock Options (#)	
Giorgio D'Urso	2005	\$348,519	\$50,000	—	\$906,000 ⁽¹⁾
Chief Executive Officer	2004	\$348,519	—	—	—
	2003	\$348,519	—	—	—
Duane M. Steele	2005	\$165,801	—	10,000	\$211,200 ⁽¹⁾
Vice President Business Development	2004	\$157,794	—	—	—
	2003	\$150,280	\$10,233	10,233	—
Mark S. Deutsch	2005	\$116,024	—	10,000	\$ 63,360 ⁽¹⁾
Chief Financial Officer	2004	\$110,385	—	—	—
	2003	\$107,170	\$ 5,116	5,116	—

(1) In July 2005, we offered each holder of options to purchase shares of our common stock, which were granted under our 1999 Stock Option Plan, the opportunity to participate in a program whereby we would

cancel 50% of such option holder's options in exchange for a cash payment to such holder of \$3.52 per share (except for the options of Mr. D'Urso, for which he would receive a cash payment of \$3.02 per share), such option holder would then exercise all of his or her remaining options by paying to us the exercise price, and such option holder would agree to hold all of the shares of our common stock received upon exercise for a period of at least one year. All but one of the option holders under the 1999 Stock Option Plan elected to participate in this program. The participating option holders held a total of 998,795 options under the 1999 Stock Option Plan (including, without limitation, 600,000 options owned by Mr. D'Urso, 120,000 options owned by Mr. Steele and 36,000 options owned by Mr. Deutsch), all of which options were fully vested, had an exercise price of \$0.73 per share and had an expiration date in the second (and, in one case, the third) quarter of 2006. Under this program, we paid Mr. D'Urso \$906,000 for the cancellation of 50% of his options and Mr. D'Urso paid us \$219,000 in connection with the exercise of his remaining options under the 1999 Stock Option Plan. Under this program, we paid Mr. Steele \$211,200 for the cancellation of 50% of his options and Mr. Steele paid us \$43,800 in connection with the exercise of his remaining options under the 1999 Stock Option Plan. Under this program, we paid Mr. Deutsch \$63,360 for the cancellation of 50% of his options and Mr. Deutsch paid us \$13,140 in connection with the exercise of his remaining options under the 1999 Stock Option Plan.

Stock Options

The following table sets forth information concerning stock option grants made during 2005 to the executive officers named in the "Summary Compensation Table."

Stock Option Grants in Fiscal Year 2005

Name	Individual Grants				Potential Realizable Value At Assumed Annual Rate of Stock Price Appreciation for Option Term	
	Shares Underlying Stock Options Granted (#)	% of Total Options Granted to Employees	Exercise Price (\$/Sh)	Expiration Date	5%(\$)	10%(\$)
Giorgio D'Urso	—	—	—	—	—	—
Duane M. Steele	10,000	22.2%	\$4.35	July 12, 2015	\$27,357	\$69,328
Mark S. Deutsch	10,000	22.2%	\$4.35	July 12, 2015	\$27,357	\$69,328

The following table sets forth information concerning stock option exercises during 2005 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 2005 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	300,000	\$906,000	—	—	—	—
Duane M. Steele	60,000	\$211,200	12,558	57,674	—	\$30,000
Mark S. Deutsch	18,000	\$ 63,360	11,279	33,837	—	\$18,000

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, 2010.

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. From May 1998 until January 2006, Mr. Flanzraich had served as the Vice Chairman 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 20, 2006, 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.

<u>Name</u>	<u>Shares (#)⁽¹⁾</u>	<u>Percent of Class (%)</u>
Teva Pharmaceutical Industries Limited	20,000,000	72.4%
IVAX Corporation c/o Teva Pharmaceuticals USA, Inc. 425 Privet Road P.O. Box 1005 Horsham, PA 19044		
Giorgio D'Urso	324,000 ⁽²⁾	1.2%
Duane M. Steele	75,116 ⁽³⁾	*
Mark S. Deutsch	30,558 ⁽⁴⁾	*
Phillip Frost, M.D.	72,354 ⁽⁵⁾	*
Neil Flanzraich	50,000 ⁽⁶⁾	*
Jane Hsiao, Ph.D.	35,000 ⁽⁷⁾	*
Fernando L. Fernandez	25,000 ⁽⁸⁾	*
Glenn L. Halpryn	75,000 ⁽⁹⁾	*
John B. Harley, M.D.	50,000 ⁽¹⁰⁾	*
Jose J. Valdes-Fauli	60,000 ⁽¹¹⁾	*
All directors and executive officers as a group (10 persons)	797,028	2.9%

* 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 9,000 shares of common stock owned by Mr. D'Urso's wife. Mr. D'Urso disclaims beneficial ownership of the shares of common stock owned by his wife.
- (3) Includes options for 15,116 shares of common stock granted to Mr. Steele.
- (4) Includes options for 12,558 shares of common stock granted to Mr. Deutsch.

- (5) Includes (a) options for 35,000 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 Teva or IVAX. Dr. Frost has served as the Vice Chairman of Teva since January 2006. Since 1987, he has served as the Chief Executive Officer of IVAX. From 1987 until January 2006, Dr. Frost had served as the Chairman of the Board of Directors of IVAX. Dr. Frost disclaims beneficial ownership of securities held by Teva and IVAX.
- (6) Includes options for 50,000 shares of common stock granted to Mr. Flanzraich.
- (7) Includes options for 35,000 shares of common stock granted to Dr. Hsiao.
- (8) Includes options for 25,000 shares of common stock granted to Mr. Fernandez.
- (9) Includes options for 75,000 shares of common stock granted to Mr. Halpryn.
- (10) Includes options for 50,000 shares of common stock granted to Dr. Harley.
- (11) Includes options for 60,000 shares of common stock granted to Mr. Valdes-Fauli.

As of January 1, 2005, 1,895,739 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, 2005, with respect to compensation plans (including individual compensation agreements) under which shares of our common stock are authorized for issuance.

Plan category	Equity Compensation Plan Information		
	(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	747,532	\$4.22	1,879,989
Equity compensation plans not approved by stockholders	175,000	\$6.40	0
Total	<u>922,532</u>	<u>\$4.64</u>	<u>1,879,989</u>

As of December 31, 2005, 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 expired on March 13, 2006.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Upon completion of the merger with the pre-merger Diagnostics, 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. The registration rights agreement expired on March 15, 2006.

In connection with the merger with the pre-merger Diagnostics, we entered into a shared services agreement with IVAX pursuant to which IVAX would continue to provide administrative and management services previously provided by IVAX to the pre-merger 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 with the pre-merger Diagnostics, 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 an indirect subsidiary of Teva, both our directors and officers insurance as well as property insurance coverage falls within the scope of Teva's directors and officers and property insurance policies. Prior to Teva's acquisition of IVAX, both our directors and officers insurance as well as property insurance coverage fell within the scope of IVAX' directors and officers and property insurance policies. During 2005 and 2004, we paid \$617,000 and \$720,000, respectively, to IVAX for premium payments for our directors and officers insurance coverage. Additionally, during 2005 and 2004, we paid \$60,000 and \$82,000, 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 \$159,408. 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, 2005 and 2004.

	For the years ended December 31,	
	2005	2004
Audit Fees	\$280,000	\$187,500
Audit-Related Fees	65,600	—
Tax Fees	—	—
All Other Fees	—	—
Total Fees	<u>\$345,600</u>	<u>\$187,500</u>

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, 2005 and 2004
- Consolidated Statements of Operations for the years ended December 31, 2005, 2004 and 2003
- Consolidated Statements of Shareholders' Equity for the years ended December 31, 2005, 2004 and 2003
- Consolidated Statements of Cash Flows for the years ended December 31, 2005, 2004 and 2003
- 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, 2005

SCHEDULE II

**IVAX DIAGNOSTICS, INC. AND SUBSIDIARIES
VALUATION AND QUALIFYING ACCOUNTS
THREE YEARS ENDED DECEMBER 31, 2005
(In thousands)**

INVENTORY RESERVES

<u>Description</u>	<u>Balance at Beginning of Year</u>	<u>Charged to Cost and Expenses</u>	<u>Net Deductions</u>	<u>Other</u>	<u>Balance at End of Year</u>
Year ended December 31, 2003	\$796	\$291	\$(357)	\$206	\$936
Year ended December 31, 2004	\$936	143	(647)	4	\$436
Year ended December 31, 2005	\$436	301	(426)	21	\$332

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.

(3) 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:

<u>Exhibit Number</u>	<u>Description</u>	<u>Method of Filing</u>
3.1	Amended and Restated Certificate of Incorporation	Incorporated by reference to our Schedule 14A filed on June 25, 2002.
3.2	Amended and Restated Bylaws	Incorporated by reference to our Form 10-Q filed on August 9, 2002.
4.1	Specimen Common Stock Certificate	Incorporated by reference to our Form 10-K filed on April 1, 2002.
10.1	Form of Indemnification Agreement between IVAX Diagnostics, Inc. and each of its directors	Incorporated by reference to our Form 10-K filed on March 31, 2003.
10.2	Use of Name License Agreement, dated March 14, 2001, between IVAX Diagnostics, Inc. and IVAX Corporation	Incorporated by reference to our Form 10-K filed on April 1, 2002.
10.3	Shared Services Agreement, dated March 14, 2001, between IVAX Diagnostics, Inc. and IVAX Corporation	Incorporated by reference to our Form 10-K filed on April 1, 2002.
10.4*	Employment Agreement, dated October 1, 1998, between IVAX Diagnostics, Inc. and Giorgio D'Urso	Incorporated by reference to our Form 10-K filed on April 1, 2002.
10.5*	Amendment to Employment Agreement, dated February 24, 2004, between IVAX Diagnostics, Inc. and Giorgio D'Urso	Incorporated by reference to our Form 10-K filed on March 25, 2004.
10.6*	Amendment to Employment Agreement, dated July 13, 2005, between IVAX Diagnostics, Inc. and Giorgio D'Urso	Incorporated by reference to our Form 10-Q filed on August 15, 2005.
10.7	1999 Performance Equity Plan	Incorporated by reference to our Form SB-2 filed on October 6, 1999.
10.8	1999 Stock Option Plan	Incorporated by reference to our Form 10-K filed on April 1, 2002.
10.9	Form of Nonqualified Stock Option Agreement (Employee)	Incorporated by reference to our Form 10-K filed on March 31, 2005.
10.10	Form of Nonqualified Stock Option Agreement (Non-Employee Director)	Incorporated by reference to our Form 10-K filed on March 31, 2005.
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.

<u>Exhibit Number</u>	<u>Description</u>	<u>Method of Filing</u>
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.

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

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

SIGNATURES

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

IVAX DIAGNOSTICS, INC.

Dated: March 30, 2006

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.

<u>Name</u>	<u>Capacity</u>	<u>Date</u>
<u>/s/ GIORGIO D'URSO</u> Giorgio D'Urso	Chief Executive Officer, President and Director (Principal Executive Officer)	March 30, 2006
<u>/s/ MARK S. DEUTSCH</u> Mark S. Deutsch	Chief Financial Officer, and Vice President—Finance (Principal Financial Officer) (Principal Accounting Officer)	March 30, 2006
<u>/s/ PHILLIP FROST, M.D.</u> Phillip Frost, M.D.	Chairman of the Board of Directors	March 30, 2006
<u>/s/ NEIL FLANZRAICH</u> Neil Flanzraich	Director	March 30, 2006
<u>/s/ JANE HSIAO, PH.D.</u> Jane Hsiao, Ph.D.	Director	March 30, 2006
<u>/s/ FERNANDO L. FERNANDEZ</u> Fernando L. Fernandez	Director	March 30, 2006
<u>/s/ GLENN L. HALPRYN</u> Glenn L. Halpryn	Director	March 30, 2006
<u>/s/ JOHN B. HARLEY, M.D.</u> John B. Harley, M.D.	Director	March 30, 2006
<u>/s/ JOSE J. VALDES-FAULI</u> Jose J. Valdes-Fauli	Director	March 30, 2006

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,” “believes,” “expects,” “anticipates,” “intends,” “plans,” “estimates,” “projects,” “could,” “would,” “should,” or similar expressions or statements that certain events or conditions may occur. Actual results, performance or achievements could differ materially from those contemplated, expressed or implied by these forward-looking statements. These forward-looking statements are based largely on our expectations and the beliefs and assumptions of our management and on the information currently available to it and are subject to a number of risks and uncertainties, including, but not limited to, the risks and uncertainties associated with: our implementation, and the progression, of our business initiatives; our limited operating revenues and history of primarily operating losses; improved financial performance or results not occurring; 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 impact of the delay in the full commercial launch of the PARSEC™ System in the United States on our international activities associated with the PARSEC™ System; the ability of the PARSEC™ System to be available when or to perform as expected; 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, to increase our market share in the autoimmune and infectious disease testing markets and to expand into additional testing sectors, whether through organic growth, strategic initiatives or otherwise; making the PARSEC™ System our primary product; our ability to market the PARSEC™ System; our customers’ integration of the PARSEC™ System into their operations; 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 at our subsidiary in Italy, to obtain regulatory approval for these products and to include these products in the menu offered with the PARSEC™ System; the ability of our new facilities near Rome to support the launch and growth of the PARSEC™ System, hepatitis kits and other new products; our ability to launch new products in the future; our ability to consummate potential acquisitions of businesses or products; our ability to integrate acquired businesses or products; our agreements with Teva, IVAX, third party distributors and key personnel; voting control of our common stock by Teva; conflicts of interest with Teva, IVAX and with our officers, directors and employees; and other economic, competitive, governmental, technological and other risks and factors discussed elsewhere in our periodic filings with the Securities and Exchange Commission, including, without limitation, in the section entitled “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2005 which has been provided as a portion of this annual report. Many of these risks and factors are beyond our control.

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