

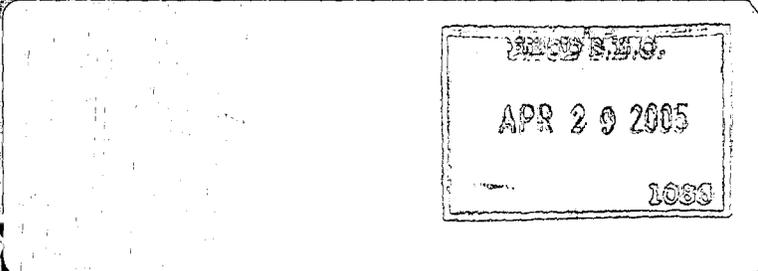
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FOR INFORMATION  
DPC®



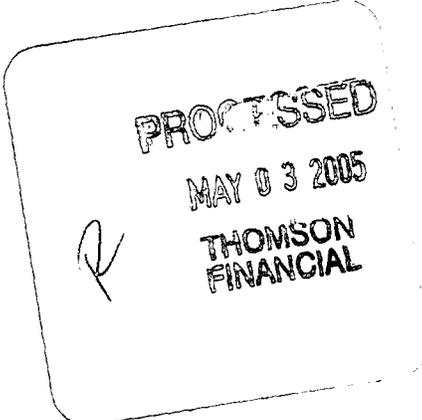
2004

ANNUAL

REPORT



DIAGNOSTIC PRODUCTS CORPORATION



## PROFILE

Diagnostic Products Corporation is a worldwide provider of immunodiagnostic systems and reagents. DPC's tests supply information vital to the detection and management of adrenal/pituitary dysfunction, allergy, anemia, bone metabolism disturbances, cancer, cardiovascular disease, diabetes, infectious diseases, inflammation, reproductive disorders, thyroid disease and therapeutic drug levels, allowing DPC to serve major clinical and veterinary diagnostic areas. Through a team now numbering over 2,400 employees, DPC maintains the product quality, service and support that have become the Company's hallmarks since its founding in 1971. Focused on providing customers with full immunoassay solutions, DPC is a world leader in the immunodiagnostics market and continues to be a company on the move.

## ABOUT THE COVER

DPC is committed to delivering to our customers the highest quality products with superior service and support. The turquoise zebra icon symbolizes DPC's uniqueness in the immunodiagnostics industry as "a company that stands out."



**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 year ended December 31, 2004

Transition report pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_  
Commission file number 1-9957



**Diagnostic Products Corporation**

(Exact name of registrant as specified in its charter)

**California**

(State or other jurisdiction of incorporation or organization)

**95-2802182**

(IRS Employer Identification No.)

**5210 Pacific Concourse Drive  
Los Angeles, California 90045**

(Address of principal executive offices)

Registrant's telephone number: **(310) 645-8200**

**Securities registered pursuant to Section 12(b) of the Act:**

| <b>Title of each class</b> | <b>Name of each exchange on which registered</b> |
|----------------------------|--|
| Common Stock, no par value | New York Stock Exchange                          |

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2).

[ YES X ] [ 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 X ] [ NO ]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K 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. [ ]

The aggregate market value of the voting stock held by non-affiliates of the registrant was approximately \$1,010,729,000 as of June 30, 2004.

The number of shares of Common Stock, no par value, outstanding as of March 4, 2005, was 29,292,046.

**Documents Incorporated by Reference**

Portions of the proxy statement for the 2005 Annual Meeting of Shareholders are incorporated by reference into Part III of this report.

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## PART I

### ITEM 1. BUSINESS

Diagnostic Products Corporation (“DPC” or the “Company”) develops, manufactures, and markets immuno-diagnostic systems and immunochemistry kits which are used throughout the world in hospital, reference and physicians’ office laboratories, as well as in veterinary, forensic, and research facilities.

The test kits utilize state-of-the-art technology, derived from immunology and molecular biology, to obtain precise, rapid identification and measurement of medically significant chemical substances that are often present at infinitesimal concentrations. These include hormones, cytokines, vitamins, drugs, transport proteins, antibodies, and biochemical markers of viruses and other microorganisms.

The main clinical applications of DPC’s immunoassays (also referred to as reagents, assays, tests or test kits) relate to the diagnosis and management of thyroid, reproductive, and cardiac disorders; allergies, infectious diseases, anemia, diabetes, and certain types of cancer; bone metabolism disorders, and therapeutic drug administration. The testing is performed *in vitro*: that is, outside the body, in samples of blood, urine, or other bodily fluids and tissues.

DPC’s IMMULITE® family of systems consist of instrumentation and software for automating the Company’s immunoassays and for integrating this process with sample handling and data manipulation steps, to improve the accuracy, efficiency, and cost-effectiveness of *in vitro* diagnostic (IVD) testing in clinical laboratories, large and small. Through a distribution arrangement with a manufacturer of chemistry systems and reagents, DPC also addresses the chemistry and laboratory automation needs of its customers.

The Company, with manufacturing facilities in the United States, the United Kingdom, and China, markets its products through a United States national sales force and through a worldwide distribution network covering over 100 countries.

Unless the context otherwise requires, the terms “DPC” and the “Company” include the Company’s consolidated subsidiaries. For information regarding forward-looking statements contained in this report and risks associated with the Company’s business, see “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations — Forward Looking Statements and Certain Risks.”

#### Automated Laboratory Systems

A systems provider, DPC designs and manufactures laboratory instruments and software to automate the performance of diagnostic assays (tests), facilitating rapid, accurate results, while reducing labor and reagent costs.

The Company has three principal immunoassay platforms. DPC’s IMMULITE 2000 and IMMULITE 2500 address the needs of high-volume laboratories, while the IMMULITE 1000 and its predecessor, the IMMULITE, serve lower volume facilities and niche markets, which include *in-vitro* fertilization clinics, urology clinics, physician office laboratories, research laboratories and veterinary clinics. At the end of 2004, over 6,300 IMMULITE/1000 systems and over 3,600 IMMULITE 2000/2500 systems had been shipped.

The original IMMULITE system was first introduced in 1993. Computer-driven, it uses a patented solid-phase wash technology and chemiluminescent detection method, which together are capable of measurements at exceptionally low concentrations, as demonstrated by DPC’s state-of-the-art “third generation” assays for TSH and PSA — key tests related to thyroid disorders and prostate cancer, respectively. The system is highly automated with respect to sample and reagent handling, incubation, washing, and substrate addition. DPC’s IMMULITE has the capacity for walk-away processing of up to 120 samples per hour, on a random access basis — meaning that it can perform any DPC test, or combination of DPC tests, on any patient sample at any time.

In 2002, the Company ceased manufacturing the IMMULITE and began manufacturing the IMMULITE 1000. This system has essentially the same operational features and runs the same tests as the IMMULITE, but it utilizes updated operating software and is capable of performing certain dilutions on-board. In addition, it has a new exterior appearance.

The IMMULITE 2000, DPC’s next addition to the IMMULITE family, was introduced in the third quarter of 1998. It has a throughput of up to 200 tests per hour, offering the medium- to high-volume laboratory increased efficiency in streamlining its testing workload. The IMMULITE 2000 can run for nearly 8 hours without having to replenish on-board supplies. This increased throughput allows DPC to participate in a higher volume segment of the market where the average reagent use per instrument exceeds that of the original IMMULITE. The IMMULITE 2000 includes advanced features such as primary tube sampling and a proprietary autodilution capability. The system can be connected to the customer’s computer system for specification of the tests to be run on each sample, as well as for reporting and archiving results. The system can also be interfaced with robotic laboratory sample handling systems

such as the Company's Sample Management System (SMS). The SMS provides customers with a bulk sample-loading platform for up to 200 samples. This high-volume sample management system improves a laboratory's workflow flexibility and productivity.

In 2004, DPC launched a major new instrument, the IMMULITE 2500. This instrument is similar to the IMMULITE 2000 (which continues to be marketed) but reduces the time it takes to get a result from certain tests, most importantly, tests used in emergency rooms to aid in the diagnosis of cardiac conditions.

DPC also provides system and reagent service and support to its customers. Innovative service features include a remote diagnostic capability that permits DPC's service facility to access any IMMULITE 2000 or 2500 worldwide for the purpose of diagnosing system problems and RealTime Service which provides the ability for an IMMULITE 2000 to monitor itself and to proactively contact the Company's service facility if it senses a potential problem. In this way, the Company may be able to solve a problem before a customer is aware that it exists. In 2004, DPC released the next evolution of RealTime Service, called RealTime Solutions. This new service allows customers to use the Internet to perform on-line quality control and monitor systems within a specified network.

Pursuant to a distribution agreement with Thermo Electron Corporation (TEC), in 2004 the Company obtained the right to distribute the Konelab clinical chemistry systems for human clinical diagnostics and veterinary testing in Spain, Portugal, Belgium, The Netherlands and Luxembourg. In France and Germany, DPC has the right to market the Konelab product line when sold together with IMMULITE systems. DPC also has nonexclusive rights to sell TEC's TC Automation, a laboratory automation product line, when sold together with the IMMULITE systems and the Konelab clinical chemistry systems.

In the first quarter of 2002, the Company obtained distribution rights from Medical Electronic Systems of Israel to a sperm analyzer that DPC markets under the name Spermalite SQA-V. The Spermalite is a stand-alone, benchtop high-performance analyzer that provides rapid reliable semen analysis in less than 75 seconds.

In 2005, the Company expects to launch an enhanced version of the SMS that will connect to two IMMULITE 2000s or 2500s, called the DPC Immunoassay Workcell. The SMS will eventually function as a universal robotic interface that can be linked to many of the workcell/automated systems available on the market.

### **Immunodiagnostic Test Kits**

DPC manufactures over 400 immunodiagnostic test kits, exploiting several technologies and assay formats. The Company's monoclonal antibody, molecular engineering, and other basic science capabilities play key roles in optimizing these immunoassays.

Chemiluminescence-enhanced enzyme immunoassays are the basis for DPC's automated IMMULITE product lines. DPC also manufactures classic radioimmunoassays (RIAs), based on double-antibody, coated-tube, and IRMA formats, as well as enzyme immunoassays (EIAs) in microplate format. Allergy testing uses a proprietary liquid-allergen technology that is now fully automated on the IMMULITE 2000. Because of the introduction of allergy testing on the IMMULITE 2000, the Company's microplate allergy format was discontinued at the end of 2003. Some of DPC's assays are available both as manual RIAs and as automated IMMULITE assays.

The automated, non-isotopic product lines represent the core of DPC's business. The IMMULITE family of assays, instruments, and service represented 85%, 89%, and 91% of sales in 2002, 2003, and 2004, respectively, a trend that is expected to continue. In fiscal year 2004, DPC's RIAs accounted for 5% of sales, while microplate allergy and other non-IMMULITE products accounted for 4%. (For additional information concerning sales by product line over the last three fiscal years, see "Notes to Consolidated Financial Statements — Note 11.")

Effective July 1, 2003, the Company sold its PathoDx line of manual tests to Remel, Inc. for \$4,900,000. The Company will continue to manufacture this product line, which consists of manual tests for strep, chlamydia, herpes, respiratory virus and cytomegalovirus, through some time in 2005.

### **Breadth of Menu**

The IMMULITE family of systems is comprised of closed systems; they will not perform other manufacturers' tests. Accordingly, a most important factor in the successful marketing of these systems is the ability to offer a broad menu of individual assays and assay *groups*, that is, tests which jointly represent decision-making panels for various disease states, such as thyroid disorders or infertility. Many of the relevant disease states represent either high-volume opportunities in the marketplace, or unique, under-served conditions that allow DPC to fill a market niche.

As of December 31, 2004, DPC had 97 IMMULITE assays available, 86 IMMULITE 2000 assays available and 63 IMMULITE 2500 assays available.

DPC believes that the IMMULITE family of systems offers one of the most extensive menus of any automated immunoassay system on the market. The Company's research and development activities continue to focus on

expanding the menu, giving special attention to complete implementations of clinically important assay groups, as well as on developing new generations of instrumentation and software. In February 2004, the Company was informed by the United States Food and Drug Administration (FDA) that it was subject to the FDA's Application Integrity Policy. As a result, the FDA will not review new test applications until the Company has successfully resolved this matter. See "Government Regulation."

### **The Spectrum of Applications**

Major clinical applications of DPC's immunoassays include the following areas, where DPC's extensive offerings on the IMMULITE family of systems have enabled the Company to achieve a significant presence in various types of laboratories, large and small.

**Thyroid Disorders** — For many hospital and clinical reference laboratories, thyroid testing is a mainstay of their routine immunoassay work. DPC offers a spectrum of assays for assessing and monitoring thyroid status on all of its immunoassay systems. The menus include not only assays for free and total thyroid hormones, but also assays with "third generation" capability for thyroid stimulating hormone (TSH) and assays for thyroid autoantibodies and other relevant analytes. The Company believes that this combination represents a high-quality solution for thyroid testing.

**Therapeutic Drug Monitoring (TDM)** — Based on industry sources, the Company believes that there is a large market for TDM assays: tests for the routine monitoring of various therapeutic drugs. Many of the most frequently monitored drugs are measured by immunoassay. DPC provides tests for Carbamazepine, Digitoxin, Digoxin, Gentamicin, Phenobarbital, Phenytoin, Theophylline, Tobramycin and Valproic Acid.

**Infertility, Pregnancy** — DPC provides a broad spectrum of assays for reproductive hormone testing, supplemented by studies to aid in the interpretation of results and software to facilitate data manipulation, when appropriate. Some of DPC's assays reflect the special needs of fertility clinics and in vitro fertilization (IVF) centers. Others are important for the routine assessment of osteoporosis and hormone balance in postmenopausal women and aging men. DPC offers an extensive menu of immunoassays for maternal and fetal diagnosis, monitoring, and risk assessment. The Company's menu relates to medical conditions in many phases of reproductive life in men, women, and children of all ages.

**Cancer** — DPC has automated a large number of assays for "tumor markers" on the IMMULITE system family. The Company has a number of important offerings, including "third generation" assays capable of measuring the extremely low PSA concentrations encountered after radical prostatectomy.

**Infectious Diseases** — Infectious disease testing is a growing segment of the IVD market and one that has historically been performed manually. DPC addresses this market with a broad menu of assays, including a panel of Hepatitis B assays, which is attractive to the U.S. market, and some esoteric assays, e.g. for *H. pylori*, an organism responsible for stomach ulcers.

**Allergy** — Traditionally in-vitro allergy testing has required special laboratory equipment and has been time- and labor-intensive, and somewhat error-prone due to the lack of full automation. With its patented liquid-allergen technology, DPC believes it is one of the leading suppliers of in vitro allergy test kits. In 2000, the Company introduced assays for selected allergy screening panels on the IMMULITE. In September 2001, DPC introduced a broad spectrum of assays for individual allergens on the IMMULITE 2000, making it possible for laboratories to perform high-volume allergy testing along with other routine immunoassays on a fully automated system. The IMMULITE 2000 and 2500 can provide tests for over 350 allergens and panels, representing over 98% of allergy requests. As a complement to IMMULITE 2000 Allergy, DPC has developed a product line (AlaBLOT®) of confirmatory Western blotting assays.

**Inflammatory Conditions** — Cytokines, often referred to as "hormones of the immune system," represent potentially important disease markers, which are being actively investigated in major centers throughout the world. In Europe and Japan, assays for clinically relevant cytokines are already in routine use, e.g. for the management of bacterial sepsis (blood poisoning) in intensive care units. DPC believes that it is the only company to offer a significant menu of cytokine assays in an automated format. These tests include an automated immunoassay for LBP (Lipopolysaccharide Binding Protein), a marker of inflammation reflecting systemic exposure to gram-negative bacteria, for which DPC has an exclusive license, and automated tests for the inflammatory markers IL-6, IL-8, IL-2R and TNF-alpha.

**Cardiovascular Disease** — Cardiovascular disease is a leading cause of morbidity and mortality in developed nations and as such represents an important field of healthcare diagnostics. On the IMMULITE family of systems, DPC offers a comprehensive cardiac menu on a single platform. The three principal assays required on an emergency basis due to their role in diagnosing acute myocardial infarction (Troponin I, CK-MB, and Myoglobin) have been implemented on the IMMULITE with *Turbo* software, which reduces the assay time to fifteen minutes, along with other tests needed in an emergency room or intra-operative setting (HCG, PTH). The Company has also implemented

these three cardiac assays with reduced assay time on the IMMULITE 2500. Additional assays, including High Sensitivity CRP and Homocysteine, put the Company in an excellent position to address all aspects of cardiac testing, from diagnosis and patient management to risk assessment.

### **Research and Development Activities**

The Company devotes substantial resources to research and development to update and improve its existing products, as well as to develop new products and technologies. In addition to developing and adding allergy testing capabilities to the IMMULITE 2000, the Company's research and development activities include the development of the next generation IMMULITE system and new versions of operating software for both the IMMULITE and the IMMULITE 2000/2500 and new assays for the IMMULITE family of systems. R&D capabilities in the United States include fully-staffed departments in organic synthesis, biochemistry, antisera/hybridoma, protein chemistry, molecular biology, and infectious disease, method development, instrumentation, software, and technology development. During the years ended December 31, 2002, 2003 and 2004, the Company spent \$36,817,000, and \$40,677,000, and \$45,277,000, respectively, on research and development.

The Company is engaged in an aggressive development program for new instrument systems, all focusing on providing improved productivity for the end users. This includes further development of sample handling devices and robotic interfaces for connections to laboratory systems to enhance the functionality of existing IMMULITE systems; the IMMULITE 3000, a very-high-throughput immunoassay system incorporating several new technologies to deliver optimal assay performance; and the IMMULITE 1500, a scaled-down version of the IMMULITE 3000. In addition, the Company continues to explore new potential technology applications for its business.

### **Manufacturing and Service**

The Company's principal test kit manufacturing facility is located in Los Angeles, California. Approximately 25% of test kit production is conducted at the EURO/DPC facility in the United Kingdom. The Company's European manufacturing facilities enable the Company to improve its competitiveness in the European Economic Area (EEA) by minimizing import duties and freight charges. Certain RIA kits are also manufactured by DPC in China.

DPC's instrument division in New Jersey designs and manufactures IMMULITE instrumentation and engages in software development. Component parts, such as computer hardware, are supplied by original equipment manufacturers. The Company provides a one-year warranty that covers parts and labor. Underwriter's Laboratories Inc. (UL), an internationally recognized independent standards organization, lists the IMMULITE systems. The Company's and its distributors' technical service personnel install new units, train customers in the use of the system, and provide maintenance and service for the instrumentation.

The EURO/DPC Instrumentation Division in the United Kingdom manufactures certain components of the IMMULITE and IMMULITE 2000 instruments that are then assembled into the final instrument in New Jersey.

DPC's Los Angeles and New Jersey facilities are International Standards Organization (ISO) 9001 and 13485 registered. ISO is an internationally recognized independent standards organization. Euro/DPC Limited, the Company's wholly-owned manufacturing subsidiary in Wales, was the first immunodiagnostics company in the world to be registered under British Standard (BS) 5750 and is also registered to ISO 9002 and ISO 13488 standards. The China facility is registered to ISO 9002

DPC provides technical support for all its products, including reagents, instruments, and software, via telephone and on-site service. In 2002 DPC introduced RealTime Service on the IMMULITE 2000 system and subsequently on the IMMULITE 2500. RealTime Service is the Company's proprietary software that connects an installed IMMULITE instrument to DPC's technical support department through a secure network connection to provide constant 24-hour monitoring and support. Should a particular system function begin to fail or degrade, an alert will be sent to a technical support representative. In 2004, DPC released its RealTime Solutions software, a new service that allows customers to use the Internet to perform on-line quality control and to monitor systems within a specified network.

### **Marketing and Sales**

The Company's customers are hospital, clinical, forensic, research, reference, and veterinary laboratories, as well as doctors' offices and U.S. government agencies. The Company markets its products in the United States directly to laboratories and hospitals through its own sales force, and also through group purchasing organizations. The Company sells to the U.S. doctors' office market through independent distributors as well as through its own sales force. Sales personnel and distributors are trained to demonstrate the Company's product line in the customer's laboratory and are supported by the Company's Los Angeles and New Jersey-based technical services departments.

No customer accounted for more than 10% of consolidated revenue for any of the three years ended December 31, 2002, 2003 and 2004.

The Company's products are sold on a worldwide basis through distributors in over 100 foreign countries. These distributors, including affiliated distributors, also sell other manufacturer's products that are not directly competitive with the Company's products. The following chart sets forth the percentage of total sales and total net income for the last three years for each of the Company's foreign geographic segments.

|                                     | <u>United<br/>Kingdom</u> | <u>German<br/>Group (1)</u> | <u>Brazilian<br/>Group (2)</u> | <u>Other</u> |
|-------------------------------------|---------------------------|-----------------------------|--------------------------------|--------------|
| <b>Percent of Total Sales:</b>      |                           |                             |                                |              |
| 2004                                | 20.3%                     | 13.1%                       | 9.0%                           | 22.1%        |
| 2003                                | 17.5%                     | 13.8%                       | 8.4%                           | 22.7%        |
| 2002                                | 13.8%                     | 12.5%                       | 9.0%                           | 21.8%        |
| <b>Percent of Total Net Income:</b> |                           |                             |                                |              |
| 2004                                | 34.3%                     | 3.4%                        | 2.9%                           | 16.9%        |
| 2003                                | 22.4%                     | 3.4%                        | 1.3%                           | 13.7%        |
| 2002                                | 20.0%                     | 1.3%                        | -1.9%                          | 7.0%         |

(1) Includes distributors located in Croatia, Czech Republic, Poland, Slovakia and Slovenia.

(2) Includes distributors located in Bolivia, Costa Rica, Dominican Republic, Guatemala, Panama, Uruguay and Venezuela.

See Notes 4 and 11 of Notes to Consolidated Financial Statements and "Management's Discussion and Analysis of Financial Condition and Results of Operations" for information regarding foreign operations.

Sales of test kits to customers and distributors are made against individual purchase orders as well as through master purchase arrangements. Products are shipped directly from the Company's facilities in Los Angeles and Wales and are generally delivered domestically within 24 hours and overseas within 48 hours of receipt of order. The Company sells, leases, or rents the IMMULITE instrumentation to hospitals and reference laboratories that perform volume testing. The Company's backlog at any date is usually insignificant and not a meaningful indicator of future sales.

The Company's foreign operations are subject to various risks, including exposure to currency fluctuations, political and economic instability, and trade restrictions. Because the Company's consolidated foreign distributors' sales are in the respective local currencies, the Company's consolidated financial results are affected by foreign currency translation adjustments. In addition, the price competitiveness of the Company's products abroad is impacted by the relative strength or weakness of the U.S. dollar. See "Management's Discussion and Analysis of Financial Condition and Results of Operations" and Note 1 of Notes to Consolidated Financial Statements.

### **Proprietary and Other Rights**

Substantially all of the Company's products are based on proprietary technologies and know-how. The Company holds various U.S. and foreign patents, including patents on the washing process used in the IMMULITE system that expire in 2009 and patents on its novel liquid-based amplification methodology which forms the basis of the allergy product line which expire in 2005. The Company also obtains licenses for chemical components and technologies used in certain of its assays. The Company has patents pending with U.S. and foreign regulatory agencies.

Patents that may be granted to others in the future could inhibit the Company's expansion or entry into certain areas, or require it to pay royalty fees to do so. Because of rapid technological developments in the immunodiagnostic industry with concurrent extensive patent coverage and the rapid rate of issuance of new patents, certain of the Company's products may involve controversy concerning infringement of existing patents or patents that may be issued in the future.

The Company purchases certain chemical compounds that are key components in the IMMULITE system from Lumigen, Inc., the sole supplier of these chemical compounds. The Company owns a 10% interest in Lumigen, Inc. and accounts for this interest using the equity method because the Company has the ability to exert significant influence as a result of its representation on Lumigen's Board of Directors and because its purchases from Lumigen are significant to Lumigen. The Company has the non-exclusive right to use these chemical compounds for the duration of the underlying patents, the last of which expires in 2017, in return for a royalty payable to the owners of

the patents. The royalty is based solely on DPC's sales of diagnostic reagents which use the chemical compounds, and there is no minimum royalty due or milestones which must be achieved.

The Company's business and financial condition could be materially adversely affected if Lumigen, Inc. was unable to meet the Company's supply requirements. In such an event, there is no assurance that the Company would be able to obtain alternative components that have the same performance characteristics or that the cost of such alternatives would not exceed the amounts charged by Lumigen.

### **Government Regulation**

The Company's business is affected by government regulations both in the United States and abroad, in particular Western Europe and Japan, aimed at containing the cost of medical services. These regulations have generally had the effect of inhibiting the growth rate of the immunodiagnostic industry. The Company believes that *in vitro* diagnostic (IVD) testing is an important tool for reducing health expenditures. By providing early diagnosis and therapy management, IVD tests can reduce the high costs of hospitalization, surgery, and recovery. In response to cost containment measures, hospitals and laboratories have consolidated and have sought to increase productivity by replacing high cost labor with automated testing systems. The Company's automated systems address these market needs. The Company also seeks to develop more rapid and sensitive tests, such as DPC's Third Generation TSH assay, that can eliminate the need for redundant testing.

Manufacturers of immunodiagnostic tests and other clinical products intended for use as human diagnostics are governed by FDA regulations as well as regulations of state agencies and foreign countries. Under FDA regulations, medical devices are classified into Class I, II, or III, depending on the level of risk and to identify the level of regulatory control that is necessary to assure their safety and effectiveness. The classification of the device generally will determine the type of marketing authorization (either pre-market notification (510(k)) or pre-market approval (PMA)), if any, the manufacturer must complete in order to obtain FDA clearance/approval to market the product. Pre-market notification (510(k)) is the mode employed to market Class I and II and some Class III devices intended for human use in the U.S., and most of DPC's products are cleared for marketing this way. DPC must submit a 510(k) to the FDA at least 90 days before marketing a product unless the device is exempt from 510(k) requirements. The purpose of the 510(k) submission is to demonstrate to the FDA that the device to be marketed is substantially equivalent to a legally marketed device for the same intended use that is not subject to pre-market approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and support their substantial equivalence claims with respect to intended use and product performance. Some 510(k) notifications must be supported by clinical data. FDA must notify the applicant that the 510(k) submission complies with applicable requirements before the product can be marketed.

A PMA requires demonstration of reasonable assurance of safety and effectiveness through the submission of clinical testing and other data. This requires an in-depth review and approval by the FDA (as opposed to a determination of substantial equivalence). The process typically takes about one year to complete after submission of the PMA application, but can take longer. Fewer than 10% of DPC's test kits have been subject to the PMA process.

In February 2004, the Company was informed by the FDA that, based on inspectional findings that included data integrity and procedural issues related solely to DPC's 510(k) application for the IMMULITE Chagas test, the Company was subject to the FDA's Application Integrity Policy ("AIP"). The FDA suspended its review of all applications submitted by the Company and will not review any future applications until the FDA determines that the Company has resolved these issues, although studies to support future applications can be conducted while on AIP. The AIP may be invoked when the FDA determines that there are serious questions as to the reliability of data submitted by applicants. The AIP sets forth corrective actions by which applicants may seek to restore the FDA's confidence in the integrity of data in their applications and permit the agency to proceed with review of such applications.

With respect to DPC, the FDA stated that in connection with the Company's Chagas test 510(k) application, among other things, the Company had failed to properly report and monitor clinical study data and that there were record keeping deficiencies. To address the AIP issues, the Company was audited by a third party, whose report has been submitted to the FDA. The Company also developed and implemented a corrective action plan that was submitted to the FDA. The Company has requested the FDA to take any action necessary to remove it from the AIP, which may include an inspection by the FDA. The Company believes that the AIP issues will be resolved with the FDA and hopes that to occur in the next few months. The FDA's application of the AIP to DPC does not restrict DPC from introducing new tests outside of the United States. However, the Company's inability to introduce new tests in the United States during the pendency of the AIP may have a negative impact on future sales and profits. See "Management's Discussion and Analysis of Financial Condition and Results of Operations."

The Company's U.S. manufacturing facilities and its Wales facility are licensed by the FDA and must be operated in conformance with the FDA's Good Manufacturing Practices ("GMP") regulations governing medical devices. The GMP regulations require that manufacturers of finished medical devices maintain a quality system that complies with the Quality System Regulation of the FDA. These regulations include controls over production, packaging, labeling, auditing, employee training, and record keeping. FDA periodically inspects device companies for compliance with the GMP regulations. FDA also regulates clinical investigations. These regulations increase the time, difficulty and costs associated with product development and production. The failure to comply with the FDA requirements can result in delay in obtaining authorization to sell products, seizure or recall of products, suspension or revocation of authority to manufacture or sell products, and other civil or criminal sanctions. The U.S. manufacturing facilities are also subject to state licensing requirements. The Company is regulated by the California Department of Health Services with respect to its possession and use of radioactive substances and by the U.S. Drug Enforcement Agency with respect to the use and storage of controlled drugs and pharmaceuticals.

The European Union (EU) requires a quality system in accordance with the international quality standard ISO 13485:2003 for device manufacturers under the In Vitro Diagnostic Medical Devices Directive (98/79/EC)(the "Directive"). Medical devices compliant under the Directive may bear the "CE" mark for free movement and trade within the EU. Since June 2000, the Company has been qualified to apply the "CE" mark to most of its in vitro diagnostic test kits and instruments as mandated by the Directive. Many other countries outside of the EU have accepted the "CE" mark to fulfill their local requirements or are developing equivalent regulations. The United Kingdom, Canada and many Latin American and Asian countries require compliance with ISO 13485 to allow access to their markets. DPC meets and is registered to the ISO 13485:2003 standard.

### **Competition**

The Company's major competitors are broad-based health care companies such as Roche Diagnostics, Abbott Diagnostics (Abbott Laboratories), Bayer, Johnson & Johnson, Beckman Coulter, and Sweden Diagnostics (formerly Pharmacia in Sweden). The Company competes on a worldwide basis with a number of large corporations that sell diversified lines of products, including immunodiagnostic products, for laboratory, medical, and hospital use. The fact that these companies offer diversified products to the laboratories at times puts the Company at a competitive disadvantage.

There are currently over 30 domestic suppliers of immunodiagnostic kits. The Company believes that competition in immunoassay testing is based on quality, service, product convenience, and price and that product innovation is an important source for change in market share.

The principal competitive factors in automated systems are size of menu (the number of assays that can be performed on the system), ease of use, and price (equipment cost, service, and reagent cost). The Company's IMMULITE system currently offers one of the widest menus of any automated system and the Company is focusing its development efforts on expanding this menu.

### **Employees**

As of December 31, 2004, the Company (including its consolidated subsidiaries) had 2,406 employees, including 808 in manufacturing, 414 in research and development, 869 in marketing and sales, and 315 in administration. None of the Company's employees are represented by a labor union, and the Company considers its employee relations to be good. The Company has experienced no significant problems in recruiting qualified technical and operational personnel.

### **Additional Company and Corporate Governance Information**

The Company's reports on Form 10-K, Form 10-Q and Form 8-K, and amendments thereto, are available on the Company's website, [www.dpcweb.com](http://www.dpcweb.com), as soon as reasonably practicable after filing with, or furnishing to, the SEC. The following information is also available on our website, [www.dpcweb.com](http://www.dpcweb.com), and in print on request of any shareholder:

- Code of Business Conduct
- Code of Ethics which applies to our Chief Executive Officer, Chief Financial Officer, Controller, and other finance employees. If we make any substantive amendments to this Code, or grant any waivers, including any implicit waivers, from a provision of the Code to our Chief Executive Officer, Chief Financial Officer, or Controller, we will disclose the nature of such amendment or waiver on our website or in a report on Form 8-K.

- Corporate Governance Guidelines
- Audit Committee Charter
- Compensation Committee Charter
- Nominating/Governance Committee Charter

In 2004, the Chief Executive Officer submitted to the New York Stock Exchange (NYSE) an annual certification that, as of the date thereof, he was unaware of any violation by the Company of the NYSE's corporate governance listing standards.

## ITEM 2. PROPERTIES

The following is a list of significant properties owned and leased by the Company and its consolidated subsidiaries as of December 31, 2004:

| Location                    | Size                              | Owned/Leased        | Uses  |
|-----------------------------|-----------------------------------|---------------------|---|
| Los Angeles, California     | 170,000 sq. ft.                   | Owned               | Corporate offices, research and development, manufacturing, and sales |
| Los Angeles, California     | 116,000 sq. ft.                   | Leased <sup>1</sup> | Manufacturing, warehousing, distribution                              |
| Los Angeles, California     | 60,000 sq. ft.                    | Owned               | Manufacturing and warehousing   |
| Los Angeles, California     | 32,000 sq. ft.                    | Leased              | Warehousing   |
| Central California          | 80 acres                          | Owned               | Raw material processing   |
| Flanders, New Jersey        | 88,000 sq. ft.<br>on 26.382 acres | Owned <sup>2</sup>  | Research, manufacturing, and distribution                             |
| Glyn Rhonwy, Wales, U.K.    | 110,000 sq. ft.                   | Owned               | Manufacturing and distribution  |
| Paris, France               | 10,032 sq. ft.                    | Leased              | Distribution  |
| São Paulo, Brazil           | 19,650 sq. ft.                    | Leased              | Distribution  |
| Bad Nauheim, Germany        | 56,500 sq. ft.                    | Owned               | Distribution  |
| Humbeek-Grimbergen, Belgium | 5,000 sq. ft.                     | Owned               | Distribution  |
| Breda, Netherlands          | 27,500 sq. ft.                    | Owned               | Distribution  |
| Madrid, Spain               | 10,226 sq. ft.                    | Leased              | Distribution  |
| Melbourne, Australia        | 15,500 sq. ft.                    | Owned               | Distribution  |
| Tianjin, China              | 20,729 sq. ft.                    | Owned               | Manufacturing and distribution  |
| Drammen, Norway             | 8,000 sq. ft.                     | Owned               | Distribution  |
| Goteborg, Sweden            | 11,970 sq. ft.                    | Owned               | Distribution  |

(1) This facility is currently on a month-to-month lease while the Company evaluates its space requirements after the move to the new executive offices in September 2004. See "Item 13. Certain Relationships and Related Transactions."

(2) This facility (opened in December 2001) is being expanded to 150,000 sq. ft. to meet future needs.

### **ITEM 3. LEGAL PROCEEDINGS**

For information concerning certain legal proceedings, see “ ITEM 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations - Sales” and Note 8 of Notes to Consolidated Financial Statements.

In late July 2004, the Company was served with a subpoena requiring it to produce to the Federal grand jury for the Central District of California, documents relating to trading in the Company’s securities and the exercise of options by officers, directors and employees of the Company between December 30, 2003 and April 1, 2004. The subpoena also seeks all documents relating to the FDA’s review of the Company’s diagnostic test to detect Chagas and any audits or reviews by the FDA between 2000 and the present relating to the Company’s products. See “Item 1. Business – Government Regulation.” Finally, the subpoena seeks the personnel file of a former Company employee. The Company is cooperating with the United States Attorney and the SEC regarding these matters. An independent committee of the Board of Directors has conducted an investigation of the trading issues and has presented its findings and conclusions to the United States Attorney and the SEC. Although it is in the early stages of the process, management believes the ultimate resolution of this matter will not have a material financial impact to the Company.

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

During the fourth quarter of the last fiscal year, no matter was submitted to a vote of the security holders.

## PART II

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

The Common Stock of the Company is listed on the New York Stock Exchange and traded under the symbol DP.

The following table sets forth the quarterly high and low price of the Company's Common Stock and quarterly dividends per share paid during 2004 and 2003.

|                | 2004    |         |          |
|----------------|---------|---------|----------|
|                | High    | Low     | Dividend |
| First Quarter  | \$51.68 | \$41.82 | \$0.06   |
| Second Quarter | 47.38   | 40.00   | 0.06     |
| Third Quarter  | 44.04   | 37.14   | 0.06     |
| Fourth Quarter | 56.51   | 40.00   | 0.07     |

|                | 2003    |         |          |
|----------------|---------|---------|----------|
|                | High    | Low     | Dividend |
| First Quarter  | \$39.50 | \$30.00 | \$0.06   |
| Second Quarter | 42.50   | 36.16   | 0.06     |
| Third Quarter  | 44.34   | 34.70   | 0.06     |
| Fourth Quarter | 47.39   | 36.25   | 0.06     |

As of March 4, 2005, the Company had 229 holders of record of its Common Stock.

The Company did not repurchase any of its shares in 2004.

#### Equity Compensation Plan Information As of December 31, 2004

| Plan category  | Number of securities to be issued upon exercise of outstanding options, warrants, and rights | Weighted-average exercise price of outstanding options, warrants, and rights | Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) |
|--|--|--|---|
|  | (a)  | (b)  | (c)   |
| Equity compensation plans approved by security holders     | 2,132,992  | \$26.14  | 1,184,800   |
| Equity compensation plans not approved by security holders | -0-  | --   | -0-   |
| Total  | 2,132,992  | \$26.14  | 1,184,800   |

## ITEM 6. SELECTED FINANCIAL DATA

(In Thousands, except per Share Data)

### Income Statement Data

|                                      | Year Ended December 31, |           |           |           |           |
|--------------------------------------|-------------------------|-----------|-----------|-----------|-----------|
|                                      | 2004                    | 2003      | 2002      | 2001      | 2000      |
| Sales                                | \$443,173               | \$381,386 | \$324,087 | \$283,129 | \$247,605 |
| Net income                           | 61,735                  | 61,795    | 47,313    | 39,029    | 28,250    |
| Earnings per share:                  |                         |           |           |           |           |
| Basic                                | 2.12                    | 2.15      | 1.66      | 1.39      | 1.03      |
| Diluted                              | 2.06                    | 2.08      | 1.60      | 1.32      | 1.00      |
| Weighted average shares outstanding: |                         |           |           |           |           |
| Basic                                | 29,082                  | 28,731    | 28,487    | 28,128    | 27,555    |
| Diluted                              | 29,912                  | 29,679    | 29,629    | 29,474    | 28,149    |
| Dividends per share                  | \$0.25                  | \$0.24    | \$0.24    | \$0.24    | \$0.24    |

### Balance Sheet Data

|                      | Year Ended December 31, |           |           |           |           |
|----------------------|-------------------------|-----------|-----------|-----------|-----------|
|                      | 2004                    | 2003      | 2002      | 2001      | 2000      |
| Working capital      | \$211,022               | \$177,567 | \$152,649 | \$117,695 | \$104,813 |
| Total assets         | 575,181                 | 487,582   | 393,447   | 325,767   | 280,484   |
| Shareholders' equity | 484,232                 | 403,000   | 323,564   | 266,904   | 227,024   |

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

### Forward-Looking Statements

Except for the historical information contained herein, this report and the following discussion in particular contain forward-looking statements (identified by the words "estimate," "project," "anticipate," "plan," "expect," "intend," "believe," "hope," and similar expressions) which are based upon management's current expectations and speak only as of the date made. These forward-looking statements are subject to risks, uncertainties, and factors that could cause actual results to differ materially from the results anticipated in the forward-looking statements. These risks and uncertainties include:

- the Company's ability to successfully market new and existing products;
- the Company's ability to keep abreast of technological innovations and successfully incorporate them into new products;
- the Company's current dependence on sole suppliers for key chemical components in the IMMULITE assays;
- the Company's ability to address and resolve issues relating to the FDA's Application Integrity Policy on a timely basis;
- the Company's ability to have new tests reviewed and approved by the FDA;
- the risks inherent in the development and release of new products, such as delays, unforeseen costs, technical difficulties, and regulatory approvals;
- competitive pressures, including technological advances and patents obtained by competitors;
- environmental risks related to substances regulated by various federal, state, and international laws;
- currency risks based on the relative strength or weakness of the U.S. dollar;
- domestic and foreign governmental health care regulation and cost containment measures;
- political and economic instability in certain foreign markets;

- changes in accounting standards promulgated by the Financial Accounting Standards Board, the Securities and Exchange Commission, the Public Company Accounting Oversight Board, or the American Institute of Certified Public Accountants; and
- the effects of governmental or other actions relating to certain payments by the Company's Chinese subsidiary.

## Overview

DPC develops and manufactures automated diagnostic test systems and related reagent test kits that are used by hospital, reference, and physicians' office laboratories throughout the world. The Company's principal product line, IMMULITE, is a fully automated, computer-driven modular system that uses specialized proprietary software to provide rapid, accurate test results that reduce the customer's labor and reagent costs. Our immunoassay tests provide critical information useful to physicians in the diagnosis, monitoring, management, and prevention of various diseases.

DPC manufactures immunodiagnostic test kits (also called "reagents" or "assays") using several different technologies and assay formats. The IMMULITE instruments are closed systems, meaning that they will not perform other manufacturers' tests. Accordingly, a major factor in the successful marketing of these systems is the ability to offer a broad menu of assays. In addition to almost 100 IMMULITE assays, the Company sells a broad range of tests based on other technologies that can be performed manually using the customer's own laboratory equipment, such as radioimmunoassay (RIA) and enzyme immunoassay (EIA) tests.

In addition to breadth of menu, major competitive factors for the IMMULITE instruments include time-to-results (how quickly the instrument performs the test), ease of use, and overall cost effectiveness. Because of these competitive factors and the rapid technological developments that characterize the industry, the Company devotes approximately 10% of its annual revenues to research and development activities, all of which are expensed as incurred.

The Company's products are sold throughout the world directly and through affiliated and independent distributors. Historically, foreign sales (including U.S. export sales, sales to non-consolidated subsidiaries and independent distributors, and sales of consolidated subsidiaries) have accounted for more than 70% of revenues, although, since 1998, domestic sales growth has outpaced foreign sales growth.

The Company derives revenues from two principal sources: reagent (test kit) sales and IMMULITE instrument placements. The Company recognizes sales of test kits upon shipment and transfer of title to the customer.

IMMULITE instruments are placed with customers under many different types of arrangements that generally fall into the following categories: sale, lease, reagent rental, and soft placement. The Company sells instruments directly to end-users, to third party leasing companies that lease the instruments to end-users, and to independent distributors that then resell the instruments to their customers. Instrument sales, which represent the smallest component of placements, are recognized upon shipment and transfer of title. The Company also places instruments under sales-type leases, which are recorded as revenue upon shipment in an amount equal to the present value of the future minimum lease payments to be received over the lease term.

Many instruments are placed other than by outright sale or sales-type lease. The Company enters into various types of lease arrangements with customers that generally provide for terms of three to five years and periodic rental payments. Revenue on leases is recognized on a pro rata basis over the term of the lease. When an instrument is placed on a reagent rental basis, the customer agrees to pay a mark-up on reagents, but is not charged for the instrument. The Company also places instruments at no charge to the customer (soft placement) subject to the customer's agreement to purchase a minimum amount of reagents. In reagent rentals and soft placements, the only revenue recognized is based on reagent shipments. Under operating lease, rental, and soft placements, DPC continues to own the instrument that is placed with the customer and the instruments come back to the Company at the end of the rental or lease period. These instruments are generally amortized on a straight-line basis over five years and maintenance costs are expensed as incurred. The Company also enters into service contracts with customers and recognizes service revenue over the related contract life (related costs are expensed as incurred).

Two important indicators used by management to evaluate financial performance are instrument shipments and reagent utilization. The number of IMMULITE instruments that the Company reports as being shipped in any period is net of instruments which come back to the Company due to the end of the related lease or rental period, or in connection with a trade-in on the purchase of a new model. Historically, the Company has rarely experienced sales returns. Therefore, no allowance has been provided. The Company refurbishes and seeks to place instruments that come back to the Company at reduced prices. Because of the different methods in which instruments are placed, total instrument sales vary from period to period based on a relative mix of placement methods, and such sales do not necessarily have a direct correlation to the number of instruments shipped during the period.

An important measure of the penetration of IMMULITE reagent sales is the average amount of reagent sales sold per instrument shipped referred to as, "reagent utilization". It takes a number of weeks or months after an instrument is shipped for it to become fully functional with regard to reagent utilization because of the time it takes for the customer to become familiar with the operation of the instrument and all of the tests a customer can run on the instrument. The Company calculates reagent utilization for a fiscal period by dividing IMMULITE reagent sales for the period by the total number of instruments shipped as of the end of the previous fiscal period.

## Results of Operations

### SUMMARY FINANCIAL DATA

(Dollars in Thousands, Except Per Share Data)

|   | <u>2004</u>      | <u>% change</u> | <u>2003</u>      | <u>% change</u> | <u>2002</u>      |
|---|------------------|-----------------|------------------|-----------------|------------------|
| Sales   | \$ 443,173       | 16.2%           | \$ 381,386       | 17.7%           | \$ 324,087       |
| Gross Profit  | 249,828          |                 | 217,022          |                 | 186,341          |
| % of sales  | 56.4%            |                 | 56.9%            |                 | 57.5%            |
| Operating Expenses:                                 |                  |                 |                  |                 |                  |
| Selling   | 77,624           |                 | 64,090           |                 | 53,471           |
| Research and Development                            | 45,277           |                 | 40,677           |                 | 36,817           |
| General and Administrative                          | 47,790           |                 | 34,928           |                 | 30,682           |
| Gain on Sale of Product Line                        | -                |                 | (4,218)          |                 | -                |
| Equity in Income of Affiliates                      | (8,451)          |                 | (6,064)          |                 | (3,841)          |
| Total Operating Expenses                            | <u>162,240</u>   | 25.4%           | <u>129,413</u>   | 10.5%           | <u>117,129</u>   |
| % of sales  | 36.6%            |                 | 33.9%            |                 | 36.1%            |
| Operating Income                                    | 87,588           | 0.0%            | 87,609           | 26.6%           | 69,212           |
| % of sales  | 19.8%            |                 | 23.0%            |                 | 21.4%            |
| Interest/Other Income-net                           | <u>417</u>       |                 | <u>827</u>       |                 | <u>(1,220)</u>   |
| Income Before Income Taxes and<br>Minority Interest | 88,005           |                 | 88,436           |                 | 67,992           |
| Provision for Income Taxes                          | 25,495           |                 | 26,280           |                 | 21,078           |
| Income Tax Rate                                     | 29.0%            |                 | 29.7%            |                 | 31.0%            |
| Minority Interest                                   | <u>775</u>       |                 | <u>361</u>       |                 | <u>(399)</u>     |
| Net Income  | <u>\$ 61,735</u> | -0.1%           | <u>\$ 61,795</u> | 30.6%           | <u>\$ 47,313</u> |
| Earnings per share:                                 |                  |                 |                  |                 |                  |
| Basic   | \$ 2.12          |                 | \$ 2.15          |                 | \$ 1.66          |
| Diluted   | \$ 2.06          |                 | \$ 2.08          |                 | \$ 1.60          |

## Sales

The Company's sales increased 16% in 2004 to \$443.2 million compared to sales of \$381.4 million in 2003, which was an 18% increase over 2002 sales of \$324.1 million. 2004 sales of all IMMULITE products (instruments and reagents) were \$404.8 million, a 20% increase over 2003. In 2003, sales of all IMMULITE products were \$338.0 million, a 22% increase over 2002. Sales of IMMULITE products represented 91% of 2004 sales, 89% of 2003 sales, and 85% of 2002 sales.

Various categories of IMMULITE product sales in 2004, 2003, and 2002 are shown in the following chart:

IMMULITE Product Line Sales  
(Dollars in Millions)

|                                    | 2004    | % change | 2003    | % change | 2002    |
|------------------------------------|---------|----------|---------|----------|---------|
| IMMULITE 2000/2500                 |         |          |         |          |         |
| Reagents                           | \$235.6 | 28.0%    | \$184.0 | 42.3%    | \$129.3 |
| Instruments and Service            | 40.8    | 36.0%    | 30.0    | -5.1%    | 31.6    |
| Total                              | \$276.4 | 29.2%    | \$214.0 | 33.0%    | \$160.9 |
| IMMULITE (including IMMULITE 1000) |         |          |         |          |         |
| Reagents                           | \$109.9 | 5.0%     | \$104.7 | 8.8%     | \$96.2  |
| Instruments and Service            | 18.5    | -4.1%    | 19.3    | -2.0%    | 19.7    |
| Total                              | \$128.4 | 3.5%     | \$124.0 | 7.0%     | \$115.9 |
| IMMULITE Product Line Sales        | \$404.8 | 19.8%    | \$338.0 | 22.1%    | \$276.8 |

The Company shipped a total of 977 IMMULITE systems in 2004, including 714 IMMULITE 2000 and 2500 systems and 263 IMMULITE 1000 systems. The total base of IMMULITE systems shipped grew to 10,010, including 3,658 IMMULITE 2000 and 2500 systems. This installed base of instruments and an expanding test kit menu are expected to support continued growth in the coming years. In 2003, the Company shipped a total of 880 IMMULITE systems, including 553 IMMULITE 2000 systems, and in 2002 the Company shipped a total of 1,083 systems, including 625 IMMULITE 2000 systems.

In 2004, as in the previous year, the growth of DPC's business was driven primarily by ongoing demand for the IMMULITE 2000 and the IMMULITE 2500. The IMMULITE 2500, which was launched in June 2004, reduces the time it takes to get a result from tests, most importantly tests used by emergency rooms to aid in the diagnosis of cardiac conditions. For this reason, although the 2500 has a higher price than the 2000, the 2500 may erode sales of the 2000. However the two instruments are otherwise very similar and the Company will continue to market the 2000 to a significant group of customers for which the faster test results are not critical, such as large reference laboratories. The IMMULITE 2000 and the 2500 have a longer sales process than the IMMULITE due to the higher sales price. The Company has also experienced a longer time delay between instrument placement and the ramp-up of reagent sales with the IMMULITE 2000 and the 2500, compared to the IMMULITE. Included in IMMULITE 2000/2500 equipment sales is revenue relating to the Company's sample management system (SMS), a sample-handling device that can be attached to the IMMULITE 2000/2500. The increase in instrument and service revenue in 2004 was in part due to the increased number of IMMULITE 2000/2500's placed and the increased number of instruments in service.

In the fourth quarter of 2002, the Company began shipping the IMMULITE 1000, an updated version of the IMMULITE One (together the "IMMULITE"). The number of IMMULITES shipped has declined in the last two years due to larger customers' preference for the IMMULITE 2000/2500. Even though IMMULITE instrument sales and service have declined, demand for the IMMULITE continues to be strong, and the Company believes that it remains an important complement to the higher throughput, state-of-the-art IMMULITE 2000 and 2500. The number of IMMULITE instruments shipped may continue to decline as more refurbished systems (which are not included in the total count of units shipped) become available at a price lower than that of new instruments.

The increase in reagent sales is in part due to the larger installed base of instruments as well as the weakness of the U.S. dollar. Reagent utilization on the IMMULITE 2000/2500 fell to \$17,937 in the fourth quarter of 2004 from \$18,537 in the fourth quarter of 2003. In the fourth quarter of 2002, reagent utilization on the IMMULITE 2000 was \$16,480. The decrease in 2004 was in part caused by an \$800,000 decrease in the sale of homocysteine kits, the fact that the Company did not release any new assays on the IMMULITE 2000 in 2004, the time it takes for the significant number of instruments placed in the last year to become fully utilized, and the mix of instruments going into high volume environments. The increase in 2003 was in part related to a larger test menu and the strength of the Euro relative to the dollar. Reagent utilization on the IMMULITE fell to \$4,426 in the fourth quarter of 2004 from \$4,497 in 2003, which was up from \$4,191 in 2002. Although the utilization on the IMMULITE increased in 2003, it is expected that the utilization will decline in the future as instruments are placed in lower volume environments.

Sales of the Company's mature RIA or isotopic products, \$24.1 million in 2004, were down 10% from \$26.7 million in 2003. Sales in 2003 decreased 11% from 2002. It is expected that these sales levels will decline in the future as customers move to more automated methods of testing which do not require radioactive agents.

Sales of other DPC products declined to \$6.2 million in 2004 from \$10.6 million in 2003. In 2002 sales of other DPC products were \$10.4 million. Sales of other DPC products in 2003 fell due to the introduction of allergy testing on the IMMULITE 2000, which took sales away from the Company's microplate-based allergy tests. The Company decided to cease production of its microplate-based allergy tests at the end of 2003, resulting in a reduced amount of sales in 2004. In the third quarter of 2003, the Company sold its PathoDx product line. Although the Company has agreed to continue manufacturing these products, the revenue from these products declined significantly in 2004. The Company's sales of other manufacturers' products increased to \$7.9 million in 2004 from \$6.1 million in 2003, which was a decrease from sales in 2002 of \$7.0 million. The Company announced in the fourth quarter of 2004 that it would begin distributing clinical chemistry equipment from Kone, a manufacturer of clinical chemistry and automation instrumentation, in selected markets, which may increase sales of other manufacturers' products in the future.

Domestic sales increased 18% in 2004 over 2003, and 20% in 2003 over 2002, reflecting in part the Company's continued success with larger customers and purchasing organizations and indirect distribution into smaller doctor's office laboratories. Domestic sales as a percentage of total sales were approximately 29% in 2004 and 2003 and 28% in 2002.

Foreign sales (including U.S. export sales, sales to non-consolidated foreign subsidiaries, and sales of consolidated subsidiaries) as a percentage of total sales were approximately 71% in 2004 and 2003 and 72% of sales in 2002. Europe, the Company's principal foreign market, represented 45%, 46%, and 44% of total sales in 2004, 2003, and 2002, respectively. Sales in the Company's German subsidiary, which includes the Czech Republic and Poland, increased 10.6% to \$58.1 million in 2004 from \$52.5 million in 2003, and \$40.6 million in 2002, reflecting the success of the IMMULITE 2000 product line. Sales in the Brazil region, which includes certain other Central and South American countries, accounted for approximately 9% of total sales, or \$39.7 million, in 2004, compared to \$31.9 million in 2003 and \$29.0 million in 2002. In the past, the Brazilian Real has been very volatile relative to the U.S. dollar. The exchange rate of Reals to the U.S. dollar was 2.7:1 at the end of 2004, 2.9:1 at the end of 2003, and 3.5:1 at the end of 2002. The Company has generally been able to increase prices when it has experienced significant devaluations in the Real, however, it has not been able to fully offset such currency effects.

Due to the significance of foreign sales, the Company is subject to currency risks based on the relative strength or weakness of the U.S. dollar. In periods when the U.S. dollar is strengthening, the effect of the translation of the financial statements of consolidated foreign affiliates is that of lower sales and net income. In periods when the dollar is weakening, the impact is the reverse. The Company's greatest exposure is to the Euro and the Brazilian Real. Based on the comparison of the exchange rates to the immediately preceding year, in 2002 the dollar weakened relative to the Euro and net of the negative impact of the Real the currency effect was a slight positive impact. In 2003, the dollar weakened relative to the Euro and to the Real. The net effect was a positive impact of 7% on sales. In 2004 the dollar weakened relative to both the Euro and the Real and the effect was a positive impact of 5% on sales. Due to intense competition, the Company's foreign distributors are generally unable to increase prices to offset the negative effect when the U.S. dollar is strong.

In the fourth quarter of fiscal year 2002, the Company discovered internally that certain senior managers and other employees of its Chinese subsidiary had made certain improper payments that may have violated foreign and U.S. laws. Beginning in the early 1990s, the Chinese subsidiary made cash payments and provided in kind benefits to hospital and laboratory customers of the Chinese subsidiary and to employees of such customers. Because certain of the customers were state owned enterprises and the payments may have been for the purpose, or may have had the effect, of causing those customers to purchase products from the Chinese subsidiary, these payments and benefits may have violated the U.S. Foreign Corrupt Practices Act as well as certain domestic Chinese laws. In addition, the deduction of these payments and benefits by the subsidiary on its tax returns may have been improper under the Chinese tax law, resulting in underpayments of Chinese taxes.

An independent investigation by the Company's audit committee concluded that no current members of the Company's senior management knew of or were involved in the provision of the payments and benefits. The Company has made changes in the management of the Chinese subsidiary, including replacement of the senior managers involved, and has implemented procedures and controls to address these issues and to promote compliance with applicable laws. The Company voluntarily disclosed these payment issues to the Securities and Exchange Commission (SEC) and the Department of Justice (DOJ) in the first quarter of 2003 and has been cooperating fully with these agencies in their investigations since that time.

The Company's discussions with both the SEC and the DOJ are at fairly advanced stages and include proposals that the Company pay an aggregate of approximately \$4.8 million to those agencies, consisting of \$2.0 million in fines and approximately \$2.8 million in disgorgement of profits and related interest charges. The proposals being discussed also include changes to the Company's compliance programs, independent monitoring of and reporting on

those programs for up to 36 months, entry of a cease and desist order and either a deferred prosecution agreement or a plea by the Company's Chinese subsidiary. Any settlement recommended by the staff of the SEC would be subject to approval by the Commission and any deferred prosecution or plea agreement would be subject to court approval. In the fourth quarter of 2002, the Company accrued \$1.5 million for actual and estimated costs to resolve this matter. In the third quarter of 2004, the Company accrued an additional \$1.0 million based on its revised estimates of costs that will be paid to the U.S. Government to resolve the matter. In the fourth quarter of 2004, the Company accrued an additional \$2.4 million, including \$750,000 in interest, based on the proposed settlements with the SEC and the DOJ. As of December 31, 2004, \$4.8 million remained in the accrual. In addition, the Company recorded a charge of \$1.4 million to its 2002 fourth quarter tax provision related to the non-deductibility of the payments in China. During the third quarter of 2003, the Company recorded an additional charge of \$0.9 million to its income tax provision for this and other Chinese tax-related matters. Legal expenses relating to this matter of approximately \$884,000 and \$1,712,000 have been incurred and charged to general and administrative expense during the years ended December 31, 2003 and 2004, respectively. It is anticipated that legal fees for issues related to China will decrease in 2005. The termination of the improper payments in China has had and may continue to have a significant adverse effect on future operations in China because such termination could negatively influence a significant number of the Chinese subsidiary's customers' decisions as to whether to continue to do business with that subsidiary. For the year ended December 31, 2004, the Chinese subsidiary had sales of \$8.2 million versus sales of \$9.8 million in 2003.

In February 2004, the Company was informed by the U.S. Food and Drug Administration (FDA) that, based on inspectional findings that included data integrity and procedural issues related solely to the Company's application for the IMMULITE Chagas test, the Company was subject to the FDA's Application Integrity Policy ("AIP"). See "Item 1. Business – Government Regulation." The FDA suspended its review of all applications submitted by the Company and will not review any future applications until the FDA determines that the Company has resolved these issues, although studies to support future applications can be conducted while on AIP.

To address the AIP issues, the Company was audited by a third party, whose report has been submitted to the FDA. The Company also developed and implemented a corrective action plan that was submitted to the FDA. The Company has requested the FDA to take any action necessary to remove it from the AIP, which may include an inspection by the FDA. The Company hopes that the AIP issues should be resolved with the FDA in the next few months. The FDA's application of the AIP to DPC does not restrict DPC from introducing new tests outside of the United States. However, the Company's inability to introduce new tests in the United States during the pendency of the AIP may have a negative impact on its future sales and profits.

The Company's Brazilian subsidiary is a participant along with various other companies in a number of lawsuits against the Brazilian Government claiming unlawful taxation. Historically the companies involved in these suits have had limited success in having these taxes overturned. The Company has also purchased unused tax credits for approximately \$1.0 million from an unrelated company. However, due to uncertainty related to the Company's ability to use these credits against its tax liabilities, it has fully reserved against the cost of these credits. These court cases typically take many years to be decided and the Company estimates what its most likely loss outcome will be based on the merits of the individual cases and advice of outside counsel. As of December 31, 2004, the Company has accrued amounts it believes it will have to pay. In the suit that involves the majority of the disputed taxes, in this case sales taxes, if the courts were to rule against the Company in all actions, it would create an additional liability of \$1.0 million.

### **Cost of Sales**

Gross margins are generally affected by product mix (regents vs. instruments), customer mix (foreign vs. domestic), and movement in foreign currencies. Gross margin in 2004 decreased to 56.4% from 56.9% in 2003. The decrease was due in part to a \$1.4 million dollar payment for a homocysteine license to cover customers' historical purchases of the Company's homocysteine tests, \$1.0 million of unabsorbed costs related to IMMULITE 2500 manufacturing issues in New Jersey which temporarily affected production of the IMMULITE 2500 during the fourth quarter, and approximately \$1.0 million in inventory write-downs related in part to discontinued products in particular the microplate allergy line. Gross margin decreased to 56.9% in 2003 from 57.5% in 2002. The decrease was due in part to an increase in manufacturing-related costs and the costs of services in Los Angeles, decreases in sales volume and production of instruments in New Jersey, price decreases on the IMMULITE 2000 in anticipation of the release of the IMMULITE 2500, and decreases in China. Gross margins were positively impacted by a weakening dollar. All products manufactured in the United States are sold in dollars, therefore, a weakening dollar could improve gross margins and a strengthening dollar could weaken gross margins. In 2003, the Company relocated its Brazilian distribution center to Recife from Sao Paulo, which has resulted in reduced tariffs and improved gross margins in the region.

## **Operating Expenses and Other**

Total operating expenses (Selling, Research and Development, and General and Administrative) as a percentage of sales were 38.5% in 2004, 36.6% in 2003 and 37.3% in 2002. All categories increased annually in absolute dollars to support the increased levels of sales. General and administrative expenses in 2002 included \$1.5 million for costs incurred through year-end 2002 relating to the investigation of the Chinese payments and for estimated payments and/or fines which the Company may incur to resolve issues relating to this matter. Included in general and administrative expense for 2003 is approximately \$884,000 in legal expenses related to the issues in China. In 2004 general and administrative expenses included \$2.6 million for estimated payments to the SEC and the DOJ in resolving this matter. In 2004 the Company also incurred \$1.7 million in legal expenses related to the issues in China. See Item 3. Legal Proceedings, and Note 8 of Notes to the Consolidated Financial Statements for a discussion of the Chinese subsidiary matter. In 2004 general and administrative expenses also included \$2.0 million related to the implementation of Sarbanes-Oxley Section 404 and approximately \$500,000 related to leasehold write-downs in the Los Angeles manufacturing facility that is being reconfigured. The strong Euro in 2002, 2003 and 2004 also contributed to higher selling and general and administrative expenses in those years.

Effective July 1, 2003, the Company sold its PathoDx product line of manual tests to Remel, Inc. for \$4.9 million. The Company will continue to manufacture the products for Remel for a period of up to two years after the sale. During this period, the Company will assist Remel in developing the expertise to take over the manufacturing process. The Company was paid \$4.4 million at closing and the remaining \$500,000 is being withheld until the manufacturing process has been transitioned. In the third quarter of 2003, the Company recognized a gain of \$4.2 million, which is included as a component of operating income.

Equity in income of affiliates represents the Company's share of earnings of non-consolidated affiliates, principally the 45%-owned Italian distributor. This amount increased 39% in 2004 relative to 2003 and 58% in 2003 relative to 2002, primarily due to increased earnings of the Italian distributor. In 2002, equity in income of affiliates included a \$400,000 permanent benefit due to a change in the Italian tax laws.

Net interest and other income (expense) represent the excess of interest income over interest expense and other amounts of income and expense. Net interest income and other income were \$417,000 in 2004 and \$827,000 in 2003 versus an expense of \$1,220,000 in 2002. The 2004 amount included \$750,000 in accrued interest expense related to estimated settlement amounts related to the Company's Chinese subsidiary as well as \$319,000 in foreign currency transaction gains. The 2003 amount included approximately \$1.2 million in foreign exchange gains versus \$500,000 in foreign exchange losses in 2002. In addition, in 2003, the Company experienced a \$433,000 increase in local tariffs in Brazil.

## **Income Taxes and Minority Interest**

The Company's effective tax rate (29% in 2004, 30% in 2003 and 31% in 2002) includes Federal, State, and foreign taxes. In the fourth quarter of 2002 the Company's tax provision includes an accrual of \$1.4 million relating to the possible non-deductibility of payments in China. The Company is routinely involved in federal and state income tax audits. The Company regularly evaluates potential tax exposures and establishes an accrual for amounts, which are probable of being paid. The Company believes it has adequately provided for such potential tax exposure.

Minority interest represents the 44% interest in the Company's Brazilian subsidiary held by a third party. Increases or decreases in this amount reflect increases or decreases in the profitability of the Brazilian distributor.

## **Net Income**

2004 net income of \$61.7 million (\$2.06 per diluted share) was slightly less than 2003 net income of \$61.8 million (\$2.08 per diluted share) due to the increases in cost of sales and operating expenses discussed above. In 2003 net income increased 31% over 2002 net income of \$47.3 million (\$1.60 per diluted share), primarily due to increases in sales (principally the IMMULITE product line) and gross profit that were greater than percentage increases in operating expenses. The \$4.2 million gain from the sale of the PathoDx product line had a \$0.10 per share after tax positive impact on 2003 diluted earnings per share.

## **Critical Accounting Policies and Estimates**

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets

and liabilities and 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. Management bases its estimates and assumptions, where applicable, on historical experience and on various other factors that it believes to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities.

#### *Allowance for Bad Debts*

Credit is granted to customers on an unsecured basis. The Company records an allowance for doubtful accounts at the time revenue is recognized based on the assessment of the business environment, customers' financial condition, historical collection experience, accounts receivable aging and customer disputes. When circumstances arise or a significant event occurs that comes to the attention of management, such as a bankruptcy filing of a customer, the allowance is reviewed for adequacy and adjusted to reflect the change in the estimated amount to be received from the customer. If the Company's aging of receivables balances were to deteriorate, the Company would have to record additional provisions for doubtful accounts.

#### *Allowance for Obsolete and Slow-Moving Inventories*

Inventories are stated at the lower of cost, determined on the first-in, first-out basis, or market. The Company regularly evaluates inventory for obsolescence and records a provision if inventory costs are not estimated to be recoverable in the normal course of business. If the Company's inventories were to become obsolete or slow moving, the Company would have to record additional provisions for obsolete inventories.

#### *Property, Plant and Equipment*

Property, plant and equipment is stated at cost, less accumulated depreciation and amortization, which is computed using straight-line and declining-balance methods over the estimated useful lives (3 to 50 years) of the related assets. Leasehold improvements are amortized over the shorter of their estimated useful lives or the term of the related lease. If the Company's estimate of the useful life of its property, plant and equipment changes, the Company may have to use a different life to record its depreciation and amortization.

The Company reviews property, plant, and equipment for impairment whenever events or changes in circumstance indicate that the carrying amount of an asset may not be recoverable. An impairment loss, measured by the difference in the estimated fair value and the carrying value of the related asset, is recognized when the future cash flows (based on undiscounted cash flows) are less than the carrying amount of the asset. For purposes of estimating future cash flows for possibly impaired assets, the Company groups assets at the lowest level for which there are identifiable cash flows that are largely independent of the cash flows of other groups of assets.

#### *Goodwill and Intangible Assets*

Goodwill results primarily from the Company's purchase of certain of its foreign distributors. Goodwill is tested for impairment at the reporting unit level at least annually or whenever events or circumstances indicate that goodwill might be impaired. The evaluation requires that the reporting unit underlying the goodwill be measured at fair value and, if this value is less than the carrying value of the unit, a second test must be performed. Under the second test, the current fair value of the reporting unit is allocated to the assets and liabilities of the unit including an amount for "implied" goodwill. If implied goodwill is less than the net carrying amount of goodwill, then the difference becomes the amount of the impairment that must be recorded in that year. The 2004 annual review did not result in any goodwill impairment for the Company.

Intangible assets consist of purchased technology licenses. The technology licenses are amortized on a straight-line basis over the life of the patented technology. The technology licenses had a weighted average amortization period of 13 years for purchases in 2004 and 2003.

#### *Deferred Income Taxes*

Deferred income taxes represent the income tax consequences on future years of differences between the income tax basis of assets and liabilities and their basis for financial reporting purposes multiplied by the applicable statutory income tax rate. Valuation allowances are established against deferred income tax assets if it is more likely than not that they will not be realized. The Company has deferred income tax assets for state net operating loss carry-forwards and state research and development tax credits. Such loss carry-forwards and credits expire in accordance with provisions of applicable tax laws beginning in the years 2005 through 2011. The Company maintains a valuation

allowance for the entire net operating loss and research and development tax credit carry-forwards as utilization of these losses and credits because it is more likely than not that they will not be recovered.

#### *Revenue Recognition*

The Company's revenue recognition policies are included in "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Overview." Changes in the underlying terms of the Company's various revenue arrangements could result in changes in the revenue recognition policies. Additionally, changes in the Company's sales returns experience could result in the need for a sales return allowance.

#### *Contingencies*

The Company is involved with various legal matters for which there is uncertainty relative to the outcome, including those involving the Company's Chinese and Brazilian subsidiaries. To provide for the potential exposure, the Company established accruals for unfavorable rulings that management believes are adequate. In addition, the Company is routinely involved in federal and state income tax audits. To provided for potential tax exposures, the Company maintains an allowance for tax contingencies which management believes is adequate.

#### **Liquidity and Capital Resources**

The Company has adequate working capital and sources of capital to carry on its current business and to meet its existing capital requirements. At December 31, 2004 and December 31, 2003, the Company had \$80,425,000 and \$69,843,000 in cash and cash equivalents, respectively. Included in the cash and cash equivalents at December 31, 2004 and 2003 is \$30,827,000 and \$35,000,00, respectively, of short-term, high-quality, commercial paper.

Net cash flows from operating activities were \$69.4 million in 2004, consisting of \$110.2 million provided by net income (\$61.7 million) adjusted for depreciation and amortization (\$43.6 million) and other non-cash items (\$4.9 million) included in net income, less \$40.8 million used in changes in operating assets and liabilities. The most significant elements of the net cash used in operating assets and liabilities were a \$34.7 million increase in inventories, which includes \$30.4 million in placed instruments, an \$11.2 million increase in accounts receivable which result from the Company's increased sales, less \$10.3 million provided by increases in accrued liabilities which included \$3.4 million of accruals related to the Company's Chinese subsidiary. Net cash flows from operating activities were \$66.7 million in 2003 and \$37.6 million in 2002. Net cash flows in 2003 consisted of \$93.6 million provided by net income (\$61.8 million) adjusted for depreciation and amortization (\$35.5 million) less other non-cash items (\$3.7 million) included in net income, less \$26.9 million used in changes in operating assets and liabilities. The most significant element of the net cash used in operating assets and liabilities was a \$28.4 million increase in inventories, which includes \$21.8 million in placed instruments, partially offset by an \$5.5 million increase in accrued liabilities. Net cash flows in 2002 consisted of \$77.6 million provided by net income (\$47.3 million) adjusted for depreciation and amortization (\$34.7 million) less other non-cash items (\$4.4 million) included in net income, less \$40.0 million used in changes in operating assets and liabilities. The most significant element of the net cash used in operating assets and liabilities was a \$42.5 million increase in inventories, which includes \$31.4 million in placed instruments, partially offset by an \$8.7 million increase in accrued liabilities.

Cash flows used for investing activities consist principally of additions to property, plant and equipment. Additions to property, plant, and equipment in 2004 were \$50.3 million compared to \$42.0 million in 2003 and \$12.5 million in 2002. Included in 2004 is \$21.7 million for the fit out of the Company's new building in Los Angeles and \$8.6 million for the construction and fit out of the Company's new building in the United Kingdom. Included in 2003 is approximately \$23.8 million for the purchase and fit out of the Company's new building in Los Angeles, approximately \$3.2 million for the construction of a new building in Wales, \$800,000 for the implementation of an ERP system in Wales, and \$1.0 million for manufacturing equipment in New Jersey. In 2004 the Company began an expansion of its New Jersey facility by 70,000 square feet to 160,000 square feet. This project will be completed in 2005 at an estimated cost of \$7.0 million.

The Company implemented a new computer system in Los Angeles in February 2002 at a capitalized cost of approximately \$4.8 million and in the United Kingdom in 2003 for a capitalized cost of approximately \$1 million. It is anticipated that the conversion of the computer systems in New Jersey will be completed in 2005 at a cost of approximately \$1.2 million.

The Company has a \$20 million unsecured line of credit with Wells Fargo Bank. No borrowings were outstanding at December 31, 2004, 2003 and 2002 under the line of credit. The line of credit matures July 2005, at which time the Company expects to enter into a similar borrowing agreement. The Company had notes payable (consisting of bank borrowings by the Company's foreign consolidated subsidiaries payable in the local currency, some of which are guaranteed by the U.S. parent company) of \$13.0 million at December 31, 2004 compared to \$19.4

million at December 31, 2003. The terms of the loans are described in "ITEM 7A. Quantitative and Qualitative Disclosures About Market Risk."

The Company has paid a quarterly cash dividend of \$.06 per share, on a split-adjusted basis, from 1995 until the fourth quarter of 2004. In the fourth quarter of 2004 the Company increased its quarterly cash dividend to \$.07 per share.

### Contractual Obligations and Commitments

On April 1, 2002, the Company amended its lease relating to 116,000 square feet of its Los Angeles facility. The original lease expired on December 31, 2002. The amendment extends the term of the lease for two years through December 31, 2004 and increases the rent to approximately \$.75 from \$.70 per square foot, for a total annual rent of \$1,035,000 effective January 1, 2003. The Company also has the option to extend the term for two years at \$.79 per square foot. The Company did not exercise its option but is continuing to pay rent at the existing rate of approximately \$.75 per square foot while it evaluates its space requirements. The lease is with a partnership comprised of Michael Ziering, CEO and director, and Ira Ziering, VP and director, Marilyn Ziering, VP, and other children of Mrs. Ziering who are shareholders of the Company. The rent was determined on various factors, including an independent appraisal, and the non-interested members of the board of directors approved the terms of the lease amendment unanimously.

The following table discloses the Company's obligations and commitments to make future payments under contractual obligations at December 31, 2004, which include the Company's subsidiaries' notes payable and lease commitments excluding the related party lease described above (see "Interest Rate Risks" in Item 7A below and "Note 5 - Notes Payable" of Notes to Consolidated Financial Statements).

*Dollars in Thousands*

|                                  | Payment Due by Year |                  |                  |                 |                 |
|----------------------------------|---------------------|------------------|------------------|-----------------|-----------------|
|                                  | Total               | 2005             | 2006<br>& 2007   | 2008<br>& 2009  | Thereafter      |
| Notes Payable                    | \$ 12,991           | \$ 4,145         | \$ 8,846         |                 |                 |
| Interest on Notes Payables (1)   | 829                 | 535              | 294              |                 |                 |
| Operating Leases                 | 19,309              | 7,807            | 7,211            | \$ 3,017        | \$ 1,274        |
| Purchased Technology Obligations | 4,750               | 4,750            |                  |                 |                 |
| <b>Total</b>                     | <b>\$ 37,879</b>    | <b>\$ 17,237</b> | <b>\$ 16,351</b> | <b>\$ 3,017</b> | <b>\$ 1,274</b> |

(1) Amounts presented for interest payments assume that all long-term debt obligations outstanding as of December 31, 2004 will remain outstanding until maturity, and interest rates on variable-rate debt in effect as of December 31, 2004 will remain in effect until maturity.

### New Accounting Pronouncements

In January 2003, the FASB issued FASB Interpretation No. ("FIN") 46, "Consolidation of Variable Interest Entities" ("FIN 46"). In December 2003, FIN 46 was replaced by FASB interpretation No. 46R "Consolidation of Variable Interest Entities." FIN 46R clarifies the application of Accounting Research Bulletin No. 51, "Consolidated Financial Statements," to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinate financial support from other parties. FIN 46R requires an enterprise to consolidate a variable interest entity if that enterprise will absorb a majority of the entity's expected losses, is entitled to receive a majority of the entity's expected residual returns, or both. FIN 46R was effective for special-purpose entities being evaluated under FIN 46R for consolidation on December 31, 2003 and was effective for all other entities being evaluated on March 31, 2004. The adoption of FIN 46R did not have a material impact on the Company's financial position or results of operations.

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (revised 2004) (FASB 123R), "Share Based Payment." FASB 123R will require the Company to expense share-based payments, including employee stock options, based on their fair value. The Company is required to adopt the provisions of FASB 123R effective as of the beginning of its third quarter in 2005. FASB 123R provides for a modified retroactive application. The Company is currently evaluating the financial impact, including the available alternatives of adoption.

In 2004, the FASB issued Financial Accounting Standard ("FAS") No. 151 entitled inventory costs. This Statement amends the guidance in ARB No. 43, "Inventory Pricing," to clarify the accounting for abnormal amounts

of idle facility expense, freight handling costs, and wasted material (spoilage). The provisions of this Statement shall be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company is currently evaluating the impact of the adoption of FAS No. 151 on its financial position and results of operations.

In December 2004, the FASB issued FSP 109-1, "Application of FASB Statement No. 109, "Accounting for Income Taxes", to the Tax Deduction on Qualified Production Activities Provided by the American Jobs Creation Act of 2004." The FASB staff believes that the qualified production activities deduction provided by the American Jobs Creation Act of 2004 ("the Act") should be accounted for as a special deduction in accordance with FASB Statement No. 109 ("FAS 109"). This FSP was effective upon issuance and is described in Note 7.

In December 2004, the FASB issued FSP 109-2, "Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004." The FASB staff believes that the lack of clarification of certain provisions within the Act and the timing of the enactment necessitate a practical exemption to the FAS 109 requirement to reflect in the period of enactment the effect of a new tax law. Accordingly, an enterprise is allowed time beyond the financial reporting period of enactment to evaluate the effect of the Act on its plan for reinvestment or repatriation of foreign earnings for purposes of applying FAS 109.

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The Company is exposed to certain market risks arising from transactions in the normal course of its business--principally risk associated with interest rate and foreign currency fluctuations.

### **Interest Rate Risk**

The Company periodically invests its excess cash in short-term high-quality commercial paper. At December 31, 2004, the Company had \$30,827,000 invested in such securities, which yielded an average annual return of approximately 2.47 %. The average maturity of these investments is less than one month. At December 31, 2003, the Company had \$35,000,000 invested in such securities, which yielded an average annual return of approximately 0.85%. The average maturity of these investments is less than one month.

Additionally, the Company has debt obligations at its foreign subsidiaries that mature on various dates. Substantially all of the Company's debt obligations are denominated in European currencies. The tables below presents principal cash flows translated into U.S. dollars at year end spot rates and related interest rates by fiscal year of maturity:

**Notes Payable Information December 31, 2004***U.S. Dollars in Thousands*

|                       | Expected Year of Maturity |          |      |          |
|-----------------------|---------------------------|----------|------|----------|
|                       | 2005                      | 2006     | 2007 | Total    |
| <b>Germany:</b>       |                           |          |      |          |
| Variable rate notes   | \$ 1,825                  | \$ 6,932 |      | \$ 8,757 |
| Average interest rate | 3.9%                      | 4.2%     |      | 4.1%     |
| <b>France:</b>        |                           |          |      |          |
| Fixed rate note       | 1,919                     | 1,350    | 563  | 3,832    |
| Average interest rate | 5.4%                      | 5.4%     | 5.4% | 5.4%     |
| <b>Spain:</b>         |                           |          |      |          |
| Variable rate notes   | 332                       |          |      | 332      |
| Average interest rate | 2.9%                      |          |      | 2.9%     |
| <b>Sweden:</b>        |                           |          |      |          |
| Variable rate note    | 62                        |          |      | 62       |
| Average interest rate | 4.1%                      |          |      | 4.1%     |
| <b>Netherlands</b>    |                           |          |      |          |
| Fixed rate note       | 7                         |          |      | 7        |
| Average interest rate | 7.3%                      |          |      | 7.3%     |

**Notes Payable Information December 31, 2003***U.S. Dollars in Thousands*

|                       | Expected Year of Maturity |          |          |        |          |           |
|-----------------------|---------------------------|----------|----------|--------|----------|-----------|
|                       | 2005                      | 2006     | 2007     | 2008   | 2009     | Total     |
| <b>Germany:</b>       |                           |          |          |        |          |           |
| Variable rate notes   | \$ 4,997                  | \$ 1,483 | \$ 1,226 | \$ 969 | \$ 2,262 | \$ 10,937 |
| Average interest rate | 4.1%                      | 4.0%     | 3.6%     | 3.1%   | 3.1%     | 3.6%      |
| <b>France:</b>        |                           |          |          |        |          |           |
| Fixed rate note       | 2,307                     | 1,780    | 1,252    | 481    |          | 5,820     |
| Average interest rate | 5.3%                      | 5.6%     | 5.3%     | 5.3%   |          | 5.4%      |
| <b>Spain:</b>         |                           |          |          |        |          |           |
| Variable rate notes   | 1,788                     | 106      |          |        |          | 1,894     |
| Average interest rate | 3.0%                      | 3.0%     |          |        |          | 3.0%      |
| <b>Sweden:</b>        |                           |          |          |        |          |           |
| Variable rate note    | 139                       | 139      | 139      | 139    | 162      | 718       |
| Average interest rate | 4.0%                      | 4.0%     | 4.0%     | 4.0%   | 4.0%     | 4.0%      |

**Foreign Currency Risk**

The Company may periodically enter into foreign currency contracts in order to manage or reduce foreign currency market risk. The Company's policies do not permit active trading of or speculation in derivative financial instruments. The Company's policy is to hedge major foreign currency cash exposures through foreign exchange forward contracts. The Company enters into these contracts with only major financial institutions, which minimizes its risk of credit loss. A discussion of the Company's primary market risk exposures and the management of those exposures are presented below.

The Company generates revenues and costs that can fluctuate with changes in foreign currency exchange rates when transactions are denominated in currencies other than the local currency. The Company manufactures its products principally in the United States and the United Kingdom and sells product to distributors, many of which are owned by the Company, throughout the world. Products sold from the United States are denominated in US dollars and products sold from the United Kingdom are denominated in pounds sterling. The distributors in turn have foreign currency risk related to their product purchases. Many of the Company-owned distributors purchase forward currency contracts to offset currency exposures related to these purchase commitments.

The following tables provide information as of December 31, 2004 and 2003 concerning the Company's forward currency exchange contracts related to certain commitments of its subsidiaries denominated in foreign currencies. The table presents the contractual amount, the weighted-average expiration date, the weighted-average contract exchange rates, and the values for its currency contracts outstanding.

### Foreign Currency Exchange Contracts Outstanding December 31, 2004

| Local Currency                          | U.S. Amount Buy      | Weighted-Average Forward Contract Rate per U.S. Dollar | Equivalent U.S. Dollar Value at December 31, 2004 Exchange Rates | Weighted-Average Maturity Date | Unrealized Loss at December 31, 2004 |
|---|----------------------|--|--|--------------------------------|--------------------------------------|
| Contracts for Purchase of U.S. Dollars: |                      |  |  |                                |                                      |
| Australian Dollar                       | \$ 2,700,000         | 0.7437   | \$ 2,807,996   | 05/15/05                       | \$ (107,996)                         |
| Euro                                    | 24,325,000           | 1.3105   | 25,236,011   | 05/30/05                       | (911,011)                            |
| Swedish Krona                           | 2,000,000            | 7.0153   | 1,894,218  | 05/09/05                       | 105,782                              |
| British Pound                           | 1,750,000            | 1.8786   | 1,776,048  | 04/29/05                       | (26,048)                             |
|   | <u>\$ 30,775,000</u> |  | <u>\$ 31,714,273</u>   |                                | <u>\$ (939,273)</u>                  |

### Foreign Currency Exchange Contracts Outstanding December 31, 2003

| Local Currency                           | Amount Buy           | Weighted-Average Forward Contract Rate | Equivalent U.S. Dollar Value at December 31, 2004 Exchange Rates | Weighted-Average Maturity Date | Unrealized Loss at December 31, 2003 |
|--|----------------------|--|--|--------------------------------|--------------------------------------|
| Contracts for Purchase of U.S. Dollars:  |                      |  |  |                                |                                      |
| Australian Dollar                        | \$ 1,800,000         | 0.7200                                 | \$ 1,861,000   | 04/01/04                       | \$ (61,000)                          |
| Euro                                     | 29,050,000           | 1.1826                                 | 30,606,000   | 05/19/04                       | (1,556,000)                          |
| Swedish Krona                            | 1,800,000            | 7.7165                                 | 1,919,000  | 04/03/04                       | (119,000)                            |
| British Pound                            | 1,500,000            | 1.6516                                 | 1,610,000  | 04/14/04                       | (110,000)                            |
|  | <u>\$ 34,150,000</u> |  | <u>\$ 35,996,000</u>   |                                | <u>\$ (1,846,000)</u>                |
| Contracts for Purchase of British Pounds |                      |  |  |                                |                                      |
| Euros                                    | £ 425,000            | 0.7024                                 | £ 427,000  | 01/26/04                       | -£ 2,000                             |

## ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

See Item 15 for a listing of the consolidated financial statements and supplementary data filed with this report.

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

None.

## ITEM 9A. CONTROLS AND PROCEDURES

### Disclosure Controls and Procedures

The Company's management, with the participation of the Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the Company's disclosure controls and procedures as of December 31, 2004. Based on this evaluation, the Chief Executive Officer and Chief Financial Officer of the Company have concluded that such disclosure controls and procedures were adequate and effective and designed to ensure that material information relating to the Company and its consolidated subsidiaries would be made known to them by others within those entities.

### Changes in Internal Controls Over Financial Reporting

There has been no change in the Company's internal control over financial reporting identified in connection with such evaluation that occurred during the Company's last fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting.

### **Management's Report on Internal Control Over Financial Reporting**

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Securities Exchange Act of 1934. Those rules define internal control over financial reporting as a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America (GAAP), and includes those policies and procedures that:

1. Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of the assets of the Company;
2. Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP, and that receipts and expenditures of the Company are being made only in accordance with authorizations of management and directors of the Company; and
3. Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of the Company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2004. In making this assessment, management used the criteria established in *Internal Control-Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on its assessment of those criteria, management believes that, as of December 31, 2004, the Company's internal control over financial reporting is effective.

The Company's independent registered public accounting firm has issued an audit report on management's assessment of internal control over financial reporting, which appears below.

### **REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

To the Board of Directors and Shareholders of  
Diagnostic Products Corporation  
Los Angeles, California

We have audited management's assessment, included in the accompanying Management's Report on Internal Controls Over Financial Reporting, that Diagnostic Products Corporation and subsidiaries (the "Company") maintained effective internal control over financial reporting as of December 31, 2004, based upon criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinions.

A company's internal control over financial reporting is a process designed by, or under the supervision of, the company's principal executive and principal financial officers, or persons performing similar functions, and effected by the company's board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those

policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of the inherent limitations of internal control over financial reporting, including the possibility of collusion or improper management override of controls, material misstatements due to error or fraud may not be prevented or detected on a timely basis. Also, projections of any evaluation of the effectiveness of the internal control over financial reporting to future periods are subject to the risk that the controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that the Company maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated financial statements as of and for the year ended December 31, 2004 of the Company and our report dated March 16, 2005 expressed an unqualified opinion on those financial statements.

/S/ DELOITTE & TOUCHE LLP

Los Angeles, California  
March 16, 2005

## **ITEM 9B. OTHER INFORMATION**

None.

## PART III

### ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF REGISTRANT

The information contained in the sections entitled "Election of Directors - Nominees"; "Election of Directors - Board Meetings and Committees - Audit Committee" (first paragraph); "Ownership of Common Stock - Section 16(a) Beneficial Ownership Reporting Compliance"; and "Executive Officers" in the Company's Proxy Statement for the 2005 Annual Meeting of Shareholders to be filed with the SEC by May 2, 2005 is hereby incorporated herein by reference. If such Proxy Statement is not filed by May 2, 2005, the information required by this Item will be included in an amendment to this Form 10-K to be filed by May 2, 2005.

See "Item 1. Business - Additional Company and Corporate Governance Information" for information concerning our Code of Ethics.

### ITEM 11. EXECUTIVE COMPENSATION

The information contained in the sections entitled "Election of Directors-Compensation of Directors," "Executive Compensation," and "Compensation Committee Interlocks and Insider Participation" in the Company's Proxy Statement for the 2005 Annual Meeting of Shareholders to be filed with the SEC by May 2, 2005 is hereby incorporated herein by reference. If such Proxy Statement is not filed by May 2, 2005, the information required by this Item will be included in an amendment to this Form 10-K to be filed by May 2, 2005.

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

The information contained in the section entitled "Ownership of Common Stock" in the Company's Proxy Statement for the 2005 Annual Meeting of Shareholders to be filed with the SEC by May 2, 2005 is hereby incorporated herein by reference. If such Proxy Statement is not filed by May 2, 2005, the information required by this Item will be included in an amendment to this Form 10-K to be filed by May 2, 2005.

See "Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities" for information about securities authorized for issuance under equity compensation plans.

### ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information contained in the section entitled "Related Transactions" in the Company's Proxy Statement for the 2004 Annual Meeting of Shareholders to be filed with the SEC by May 2, 2005 is hereby incorporated herein by reference. If such Proxy Statement is not filed by May 2, 2005, the information required by this Item will be included in an amendment to this Form 10-K to be filed by May 2, 2005.

### ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information contained in the second and third paragraphs of the section entitled "The Company's Auditors and Audit Fees" in the Company's Proxy Statement for the 2005 Annual Meeting of Shareholders to be filed with the SEC by May 2, 2005 is hereby incorporated herein by reference. If such Proxy Statement is not filed by May 2, 2005, the information required by this Item will be included in an amendment to this Form 10-K to be filed by May 2, 2005.

## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) Documents filed as part of Report:

1. Financial Statements:

Report of Independent Registered Public Accounting Firm.

Consolidated Balance Sheets as of December 31, 2004 and 2003.

Consolidated Statements of Income for each of the three years in the period ended December 31, 2004.

Consolidated Statements of Shareholders' Equity for each of the three years in the period ended December 31, 2004.

Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2004.

Notes to Consolidated Financial Statements.

2. Financial Statement Schedules-None.

3. Exhibits – See “Exhibit Index” which appears after the signature page of this report.

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Shareholders of  
Diagnostic Products Corporation  
Los Angeles, California

We have audited the accompanying consolidated balance sheets of Diagnostic Products Corporation and subsidiaries (the "Company") as of December 31, 2004 and 2003, and the related consolidated statements of income, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2004. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, such consolidated financial statements present fairly, in all material respects, the financial position of Diagnostic Products Corporation and subsidiaries at December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2004, in conformity with accounting principles generally accepted in the United States of America.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of the Company's internal control over financial reporting as of December 31, 2004, based on the criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated March 16, 2005 expressed an unqualified opinion on management's assessment of the effectiveness of the Company's internal control over financial reporting and an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/S/ DELOITTE & TOUCHE LLP

Los Angeles, California  
March 16, 2005

## CONSOLIDATED BALANCE SHEETS

(Dollars in Thousands, Except Share Data)

|   | December 31,      |                   |
|---|-------------------|-------------------|
|   | 2004              | 2003              |
| <b>Assets</b>   |                   |                   |
| <b>CURRENT ASSETS:</b>  |                   |                   |
| Cash and cash equivalents   | \$ 80,425         | \$ 69,843         |
| Accounts receivable (including receivables from unconsolidated affiliates of \$6,190 and \$6,701, respectively) – net of allowance for doubtful accounts of \$3,667 and \$3,195, respectively | 100,094           | 91,043            |
| Inventories   | 93,228            | 86,502            |
| Prepaid expenses and other current assets   | 5,297             | 5,500             |
| Deferred income taxes   | 4,030             | 5,413             |
| Total current assets  | 283,074           | 258,301           |
| PROPERTY, PLANT, AND EQUIPMENT - net  | 144,772           | 104,420           |
| INSTRUMENTS – net   | 82,730            | 76,497            |
| DEFERRED INCOME TAXES   |                   | 255               |
| INVESTMENTS IN AFFILIATED COMPANIES   | 39,227            | 29,822            |
| OTHER ASSETS – net  | 11,937            | 4,864             |
| GOODWILL  | 13,441            | 13,423            |
| <b>TOTAL ASSETS</b>   | <b>\$ 575,181</b> | <b>\$ 487,582</b> |
| <b>Liabilities and Shareholders' Equity</b>   |                   |                   |
| <b>CURRENT LIABILITIES:</b>   |                   |                   |
| Notes payable   | \$ 4,145          | \$ 19,369         |
| Accounts payable  | 18,391            | 20,983            |
| Accrued liabilities   | 45,644            | 31,136            |
| Income taxes payable  | 3,872             | 9,246             |
| Total current liabilities   | 72,052            | 80,734            |
| LONG-TERM LIABILITIES   | 8,846             | 1,000             |
| DEFERRED INCOME TAXES   | 5,841             |                   |
| MINORITY INTEREST   | 4,210             | 2,848             |
| <b>SHAREHOLDERS' EQUITY:</b>  |                   |                   |
| Common Stock—no par value, authorized 60,000,000 shares at December 31, 2004 and 2003; outstanding 29,230,196 shares and 28,907,969 shares, respectively                                      | 73,881            | 66,758            |
| Retained earnings   | 390,597           | 336,129           |
| Accumulated other comprehensive income  | 19,754            | 113               |
| Total shareholders' equity  | 484,232           | 403,000           |
| <b>TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY</b>   | <b>\$ 575,181</b> | <b>\$ 487,582</b> |

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS.

## CONSOLIDATED INCOME STATEMENTS

(Amounts in Thousands, Except Per Share Data)

|   | Year Ended December 31, |            |            |
|---|-------------------------|------------|------------|
|   | 2004                    | 2003       | 2002       |
| <b>SALES:</b>   |                         |            |            |
| Non-Affiliated Customers                                    | \$ 410,306              | \$ 351,455 | \$ 293,283 |
| Unconsolidated Affiliates                                   | 32,867                  | 29,931     | 30,804     |
| Total Sales   | 443,173                 | 381,386    | 324,087    |
| <b>COST OF SALES</b>  | 193,345                 | 164,364    | 137,746    |
| Gross Profit  | 249,828                 | 217,022    | 186,341    |
| <b>OPERATING EXPENSES:</b>                                  |                         |            |            |
| Selling   | 77,624                  | 64,090     | 53,471     |
| Research and Development                                    | 45,277                  | 40,677     | 36,817     |
| General and Administrative                                  | 47,790                  | 34,928     | 30,682     |
| Gain on Sale of Product Line                                |                         | (4,218)    |            |
| Equity in Income of Affiliates                              | (8,451)                 | (6,064)    | (3,841)    |
| <b>OPERATING EXPENSES-NET</b>                               | 162,240                 | 129,413    | 117,129    |
| <b>OPERATING INCOME</b>                                     | 87,588                  | 87,609     | 69,212     |
| Interest/Other Income(Expense)-Net                          | 417                     | 827        | (1,220)    |
| <b>INCOME BEFORE INCOME TAXES<br/>AND MINORITY INTEREST</b> | 88,005                  | 88,436     | 67,992     |
| PROVISION FOR INCOME TAXES                                  | 25,495                  | 26,280     | 21,078     |
| MINORITY INTEREST   | 775                     | 361        | (399)      |
| <b>NET INCOME</b>   | \$ 61,735               | \$ 61,795  | \$ 47,313  |
| <b>EARNINGS PER SHARE:</b>                                  |                         |            |            |
| BASIC   | \$ 2.12                 | \$ 2.15    | \$ 1.66    |
| DILUTED   | \$ 2.06                 | \$ 2.08    | \$ 1.60    |
| <b>WEIGHTED AVERAGE SHARES OUTSTANDING:</b>                 |                         |            |            |
| BASIC   | 29,082                  | 28,731     | 28,487     |
| DILUTED   | 29,912                  | 29,679     | 29,628     |

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS.

## CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

*(Amounts in Thousands, Except Share and Per Share Data)*

|  | Common Stock      |                  | Retained<br>Earnings | Accumulated Other<br>Comprehensive |                                |
|--|-------------------|------------------|----------------------|------------------------------------|--------------------------------|
|  | Shares            | Amount           |                      | Income (Loss)                      | Comprehensive<br>Income (Loss) |
| BALANCE, JANUARY 1, 2002   | 28,343,170        | \$ 55,068        | \$ 240,748           | \$                                 | (28,912)                       |
| Comprehensive income:  |                   |                  |                      |                                    |                                |
| Net income   |                   |                  | 47,313               |                                    | \$ 47,313                      |
| Foreign currency translation adjustment                                    |                   |                  |                      | 10,441                             | <u>10,441</u>                  |
| Total comprehensive income   |                   |                  |                      |                                    | <u>\$ 57,754</u>               |
| Income tax benefit received upon<br>exercise of certain stock options      |                   | 1,820            |                      |                                    |                                |
| Issuance of shares upon exercise of<br>stock options                       | 260,609           | 3,919            |                      |                                    |                                |
| Cash dividends (\$0.24 per share)  | -                 | -                | (6,833)              | -                                  |                                |
| BALANCE, DECEMBER 31, 2002   | 28,603,779        | \$ 60,807        | \$ 281,228           | \$                                 | (18,471)                       |
| Comprehensive income:  |                   |                  |                      |                                    |                                |
| Net income   |                   |                  | 61,795               |                                    | \$ 61,795                      |
| Foreign currency translation adjustment                                    |                   |                  |                      | 19,748                             | 19,748                         |
| Unrealized loss of foreign exchange<br>contracts--net of tax               |                   |                  |                      | (1,164)                            | <u>(1,164)</u>                 |
| Total comprehensive income   |                   |                  |                      |                                    | <u>\$ 80,379</u>               |
| Income tax benefit received upon<br>exercise of certain stock options      |                   | 1,621            |                      |                                    |                                |
| Issuance of shares upon exercise of<br>stock options                       | 304,190           | 4,330            |                      |                                    |                                |
| Cash dividends (\$0.24 per share)  | -                 | -                | (6,894)              | -                                  |                                |
| BALANCE, DECEMBER 31, 2003   | 28,907,969        | \$ 66,758        | \$ 336,129           | \$                                 | 113                            |
| Comprehensive income:  |                   |                  |                      |                                    |                                |
| Net income   |                   |                  | 61,735               |                                    | \$ 61,735                      |
| Foreign currency translation adjustment                                    |                   |                  |                      | 18,977                             | 18,977                         |
| Net change in unrealized loss on foreign<br>exchange contracts--net of tax |                   |                  |                      | 664                                | <u>664</u>                     |
| Total comprehensive income   |                   |                  |                      |                                    | <u>\$ 81,376</u>               |
| Income tax benefit received upon<br>exercise of certain stock options      |                   | 1,532            |                      |                                    |                                |
| Issuance of shares upon exercise of<br>stock options                       | 322,227           | 5,591            |                      |                                    |                                |
| Cash dividends (\$0.25 per share)  | -                 | -                | (7,267)              | -                                  |                                |
| BALANCE, DECEMBER 31, 2004   | <u>29,230,196</u> | <u>\$ 73,881</u> | <u>\$ 390,597</u>    | <u>\$</u>                          | <u>19,754</u>                  |

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS.

## CONSOLIDATED STATEMENT OF CASH FLOWS

(Dollars in Thousands)

|  | Year Ended December 31, |           |           |
|--|-------------------------|-----------|-----------|
|  | 2004                    | 2003      | 2002      |
| <b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>                                       |                         |           |           |
| Net income   | \$ 61,735               | \$ 61,795 | \$ 47,313 |
| Adjustments to reconcile net income to net cash flows from operating activities:   |                         |           |           |
| Depreciation and amortization  | 43,606                  | 35,469    | 34,741    |
| Provision for doubtful accounts  | 1,165                   | 1,110     | 625       |
| Minority interest  | 775                     | 361       | (399)     |
| Equity in undistributed income of unconsolidated affiliates - net of distributions | (5,777)                 | (5,261)   | (3,841)   |
| Deferred income taxes  | 7,232                   | 2,675     | (2,647)   |
| Income tax benefit received upon exercise of stock options                         | 1,532                   | 1,621     | 1,820     |
| Gain on sale of product line   |                         | (4,218)   |           |
| Changes in operating assets and liabilities:                                       |                         |           |           |
| Accounts receivable  | (11,170)                | (3,937)   | (5,195)   |
| Inventories  | (34,660)                | (28,377)  | (42,509)  |
| Prepaid expenses and other assets  | 2,315                   | 803       | (2,856)   |
| Accounts payable   | (1,813)                 | (4,138)   | 1,224     |
| Accrued liabilities  | 10,337                  | 5,515     | 8,710     |
| Income taxes payable   | (5,832)                 | 3,249     | 571       |
| Net cash flows from operating activities   | 69,445                  | 66,667    | 37,557    |
| <b>CASH FLOWS USED FOR INVESTING ACTIVITIES:</b>                                   |                         |           |           |
| Investment in affiliated companies   | (219)                   |           | (1,202)   |
| Additions to property, plant, and equipment  | (50,320)                | (41,965)  | (12,468)  |
| Acquisition of license agreement   |                         | (5,000)   |           |
| Proceeds from the sale of product line   | -                       | 4,218     | -         |
| Net cash flows used for investing activities                                       | (50,539)                | (42,747)  | (13,670)  |
| <b>CASH FLOWS USED FOR FINANCING ACTIVITIES:</b>                                   |                         |           |           |
| Borrowings under notes payable   | 17,145                  | 12,009    | 8,490     |
| Repayments of notes payable  | (26,234)                | (16,105)  | (8,767)   |
| Proceeds from exercise of stock options  | 5,591                   | 4,330     | 3,919     |
| Cash dividends paid  | (7,267)                 | (6,894)   | (6,833)   |
| Net cash flows used for financing activities                                       | (10,765)                | (6,660)   | (3,191)   |
| EFFECT OF EXCHANGE RATE CHANGES ON CASH  | 2,441                   | (1,701)   | 1,754     |
| NET INCREASE IN CASH AND CASH EQUIVALENTS  | 10,582                  | 15,559    | 22,450    |
| CASH AND CASH EQUIVALENTS AT BEGINNING OF PERIOD                                   | 69,843                  | 54,284    | 31,834    |
| CASH AND CASH EQUIVALENTS AT END OF PERIOD   | \$ 80,425               | \$ 69,843 | \$ 54,284 |
| <b>SUPPLEMENTAL CASH FLOW INFORMATION -</b>  |                         |           |           |
| Non cash transactions:   |                         |           |           |
| Instrument placements transferred from inventories                                 | \$ 30,438               | \$ 21,766 | \$ 31,415 |
| Cash paid during the year for income taxes   | \$ 22,756               | \$ 21,003 | \$ 18,721 |
| Cash paid during the year for interest, net of capitalized interest                | \$ 1,603                | \$ 3,056  | \$ 1,270  |

SEE ACCOMPANYING NOTES TO CONSOLIDATED FINANCIAL STATEMENTS.

## **Note 1 – Summary of Significant Accounting Policies**

### **Principles of Consolidation**

The consolidated financial statements include the accounts of Diagnostic Products Corporation and its majority-owned subsidiaries (together referred to herein as “DPC” or the “Company”) after elimination of all significant intercompany balances and transactions. The consolidated accounts include 100% of the assets and liabilities of these majority-owned subsidiaries. Minority interest represents the 44% of the Company’s Brazilian subsidiary not owned by the Company. The equity method is used to account for investments in affiliates in which we exert significant influence, generally having a 20 to 50 percent ownership interest. The Company also uses the equity method to account for its 10% interest in Lumigen Inc. because of its ability to exert significant influence as a result of its representation on Lumigen’s board of directors and because its purchases from Lumigen are significant to Lumigen.

### **Factors That May Affect Future Results**

The Company’s future operating results are dependent on its ability to research, develop, manufacture, and market innovative products that meet customers’ needs. Inherent in this process are a number of risks that the Company must successfully manage in order to achieve favorable operating results.

The Company’s products that are sold in the United States, whether manufactured in the United States or elsewhere, require product clearance by the United States Food and Drug Administration (FDA). In February 2004, the FDA’s Application Integrity Policy was applied to the Company whereby the FDA will not review new tests for approval until the related issues with the FDA are resolved.

The operations of the Company involve the use of substances regulated under various Federal, state, and international laws governing the environment. Environmental costs are presently not material to the Company’s operations or financial position.

The Company purchases certain chemical compounds that are key components in the IMMULITE system from Lumigen, Inc., the sole supplier of these chemical compounds, until the related patents expire in 2017. The Company’s business could be materially adversely affected if Lumigen, Inc. were unable to meet the Company’s supply requirements. In such an event, the Company would be required to enter into new supply agreements or use alternate technologies. If obtainable, such technology must have the same performance characteristics as the technology currently in use.

Although the Company believes that it has the products and resources needed for continuing success, future revenue and margin trends cannot be reliably predicted and may cause the Company to adjust its operations. Because of the foregoing factors, recent trends may not be reliable indicators of future financial performance.

Patents that may be granted to others in the future could inhibit the Company’s expansion or entry into certain areas, or require it to pay royalty fees to do so. Because of rapid technological developments in the immunodiagnostic industry with concurrent extensive patent coverage and the rapid rate of issuance of new patents, certain of the Company’s products may involve controversy concerning infringement of existing patents or patents that may be issued in the future.

Risks and uncertainties include the Company’s ability to successfully market new and existing products; the Company’s ability to keep abreast of technological innovations and successfully incorporate them into new products; the Company’s dependence on a sole supplier for key chemical components in the IMMULITE assays; the Company’s ability to address and resolve issues relating to the FDA’s Application Integrity Policy; the Company’s ability to have new tests reviewed and approved by the FDA; and the effects of government or other actions relating to certain payments by the Company’s Chinese subsidiary.

### **Use of Estimates**

Preparation of the consolidated financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could ultimately differ from those estimates.

### **Financial Instruments**

The fair value of the Company's financial instruments approximates cost due to their short-term nature or, in the case of notes payable, because the notes are at interest rates competitive with those that would be available to the Company in the current market environment.

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash equivalents and trade receivables. The Company's cash equivalents are in high quality securities placed with major banks. Concentrations of credit risk with respect to receivables are limited due to the large number of customers and their dispersion across worldwide geographic areas. The Company performs periodic credit evaluations of its customers' financial condition and generally does not require collateral.

### Cash Equivalents

The Company considers all highly liquid investments purchased having a maturity of three months or less to be cash equivalents. Included in cash and cash equivalents at December 31, 2004 and 2003 is \$30,827,000 and \$35,000,000, respectively, of short-term, high-quality, commercial paper.

### Accounts Receivable and Allowance for Doubtful Accounts

Credit is granted to customers on an unsecured basis. The Company records an allowance for doubtful accounts at the time revenue is recognized based on the assessment of the business environment, customers' financial condition, historical collection experience, accounts receivable aging and customer disputes. When circumstances arise or a significant event occurs that comes to the attention of management, such as a bankruptcy filing of a customer, the allowance is reviewed for adequacy and adjusted to reflect the change in the estimated amount to be received from the customer.

### Inventories

Inventories are stated at the lower of cost, determined on the first-in, first-out basis, or market. The Company regularly evaluates inventory for obsolescence and records a provision if inventory costs are not estimated to be recoverable in the normal course of business.

### Property, Plant and Equipment

Property, plant and equipment is stated at cost, less accumulated depreciation and amortization, which is computed using straight-line and declining-balance methods over the estimated useful lives (3 to 50 years) of the related assets. Leasehold improvements are amortized over the shorter of their estimated useful lives or the term of the related lease.

Property, plant and equipment consists of the following:

*Dollars in Thousands*

|   | <u>2004</u>       | <u>2003</u>       | <u>Estimated<br/>Useful Lives</u> |
|---|-------------------|-------------------|-----------------------------------|
| Land and buildings                        | \$ 114,552        | \$ 58,711         | 20-50 Years                       |
| Machinery and equipment                   | 104,245           | 79,638            | 3-5 Years                         |
| Leasehold improvements                    | 9,578             | 9,384             | 3-9 Years                         |
| Construction-in progress                  | 3,714             | 30,111            |                                   |
| Total                                     | <u>232,089</u>    | <u>177,844</u>    |                                   |
| Accumulated depreciation and amortization | <u>(87,317)</u>   | <u>(73,424)</u>   |                                   |
| Property, plant and equipment - net       | <u>\$ 144,772</u> | <u>\$ 104,420</u> |                                   |

Construction in progress at December 31, 2004 primarily represents the construction and fit out of an expansion of a building in New Jersey. Construction in progress at December 31, 2003 primarily represents the purchase and fit out of a new building in Los Angeles that was placed in service in September 2004 and the construction and fit out of a new building in the United Kingdom that was placed in service in December 2004. In accordance with Statement of Financial Accounting Standards No. 34, "Capitalization of Interest Costs," the Company capitalized interest costs associated with the above projects, which were included as part of the historical cost of the building improvements. Capitalized interest costs were \$957,000 in 2004 and none in 2003 and 2002.

The Company reviews property, plant, and equipment for impairment whenever events or changes in circumstance indicate that the carrying amount of an asset may not be recoverable. An impairment loss, measured by the difference in the estimated fair value and the carrying value of the related asset, is recognized when the future cash flows (based on undiscounted cash flows) are less than the carrying amount of the asset. For purposes of estimating future cash flows for possibly impaired assets, the Company groups assets at the lowest level for which there are identifiable cash flows that are largely independent of the cash flows of other groups of assets.

### Goodwill and Intangible Assets

Goodwill results primarily from the Company's purchase of certain of its foreign distributors. Goodwill is tested for impairment at the reporting unit level at least annually or whenever events or circumstances indicate that goodwill might be impaired. The evaluation requires that the reporting unit underlying the goodwill be measured at fair value and, if this value is less than the carrying value of the unit, a second test must be performed. Under the second test, the current fair value of the reporting unit is allocated to the assets and liabilities of the unit including an amount for "implied" goodwill. If implied goodwill is less than the net carrying amount of goodwill, then the difference becomes the amount of the impairment that must be recorded in that year. The Company's annual reviews did not result in any goodwill impairment for the Company.

Intangible assets at December 31, 2004 consist of purchased technology licenses in the amount of \$7,995,000, which is net of amortization of \$717,000. Intangible assets at December 31, 2003 consist of a purchased technology license in the amount of \$4,864,000, which is net of amortization of \$136,000. The technology licenses are amortized on a straight-line basis over the life of the patented technology. The technology licenses had an average amortization period of 13 years for purchases in 2004 and 2003. The amortization expense was \$581,000 and \$136,000 in 2004 and 2003, respectively. Amortization expense in each of the next five years is \$695,000.

### Accrued Liabilities

Accrued liabilities consists of the following:

*Dollars in Thousands*

|   | <u>2004</u>      | <u>2003</u>      |
|---|------------------|------------------|
| Payroll and benefits                      | \$ 12,170        | \$ 12,663        |
| Brazil tax contingency and other accruals | 4,818            | 4,378            |
| China contingency                         | 4,789            | 1,400            |
| Royalties                                 | 7,339            | 4,103            |
| Deferred service revenue                  | 4,876            | 3,039            |
| Other                                     | 11,652           | 5,553            |
| Total                                     | <u>\$ 45,644</u> | <u>\$ 31,136</u> |

### Foreign Currency Translation

The functional currency for foreign subsidiaries is generally the local currency. Assets and liabilities of foreign subsidiaries and affiliates are translated into U.S. dollars at the exchange rate prevailing at the balance sheet date, and income and expense accounts are translated at the weighted average rate in effect during the year. Foreign exchange translation adjustments are included as a component of comprehensive income and are accumulated in a separate component of shareholders' equity. Gains and losses resulting from foreign currency transactions are included in income. Transaction gains of approximately \$318,000 and \$1,158,000 and transaction losses of approximately \$493,000 were included in income for the years ended December 31, 2004, 2003, and 2002 respectively.

### Foreign Exchange Instruments

The Company hedges specific foreign currency exposures by purchasing foreign exchange contracts. Such foreign exchange contracts are generally entered into by the Company's foreign subsidiaries. The subsidiaries purchase foreign exchange contracts to hedge firm or anticipated commitments, denominated in other than their functional currency, to acquire inventory for resale. The Company does not engage in speculative transactions. The Company's foreign exchange contracts do not subject the Company to exchange rate risk as any gains or losses on the

transactions being hedged offset losses or gains on these contracts. On the date the Company enters into a derivative contract, management designates the derivative as a hedge of the identified exposure (fair value or cash flow hedge). For all qualifying and highly effective cash flow hedges, the changes in the effective portion of the fair value of the derivative are recorded in other comprehensive income. Total unrealized losses on foreign exchange contracts at December 31, 2004 was \$939,000, of which \$500,000 (net of income tax benefit of \$282,000) related to cash flow hedges was included in accumulated other comprehensive income. At December 31, 2003, total unrealized losses on foreign exchange contracts was \$1.8 million, of which \$1,164,000 (net of income tax benefit of \$499,000) related to cash flow hedges was included in accumulated other comprehensive income. The following tables provide information concerning the Company's forward currency exchange contracts.

#### Foreign Currency Exchange Contracts Outstanding December 31, 2004

| Local Currency                          | U.S. Amount Buy      | Weighted-Average Forward Contract Rate per U.S. Dollar | Equivalent U.S. Dollar Value at December 31, 2004 Exchange Rates | Weighted-Average Maturity Date | Unrealized Loss at December 31, 2004 |
|---|----------------------|--|--|--------------------------------|--------------------------------------|
| Contracts for Purchase of U.S. Dollars: |                      |  |  |                                |                                      |
| Australian Dollar                       | \$ 2,700,000         | 0.7437   | \$ 2,807,996   | 05/15/05                       | \$ (107,996)                         |
| Euro                                    | 24,325,000           | 1.3105   | 25,236,011   | 05/30/05                       | (911,011)                            |
| Swedish Krona                           | 2,000,000            | 7.0153   | 1,894,218  | 05/09/05                       | 105,782                              |
| British Pound                           | 1,750,000            | 1.8786   | 1,776,048  | 04/29/05                       | (26,048)                             |
|   | <u>\$ 30,775,000</u> |  | <u>\$ 31,714,273</u>   |                                | <u>\$ (939,273)</u>                  |

#### Foreign Currency Exchange Contracts Outstanding December 31, 2003

| Local Currency                           | U.S. Amount Buy      | Weighted-Average Forward Contract Rate per U.S. Dollar | Equivalent U.S. Dollar Value at December 31, 2003 Exchange Rates | Weighted-Average Maturity Date | Unrealized Loss at December 31, 2003 |
|--|----------------------|--|--|--------------------------------|--------------------------------------|
| Contracts for Purchase of U.S. Dollars:  |                      |  |  |                                |                                      |
| Australian Dollar                        | \$ 1,800,000         | 0.7200   | \$ 1,861,000   | 04/01/04                       | \$ (61,000)                          |
| Euro                                     | 29,050,000           | 1.1826   | 30,606,000   | 05/19/04                       | (1,556,000)                          |
| Swedish Krona                            | 1,800,000            | 7.7165   | 1,919,000  | 04/03/04                       | (119,000)                            |
| British Pound                            | 1,500,000            | 1.6516   | 1,610,000  | 04/14/04                       | (110,000)                            |
|  | <u>\$ 34,150,000</u> |  | <u>\$ 35,996,000</u>   |                                | <u>\$ (1,846,000)</u>                |
| Contracts for Purchase of British Pounds |                      |  |  |                                |                                      |
| Euros                                    | £ 425,000            | 0.7024   | £ 427,000  | 01/26/04                       | -£ 2,000                             |

#### Accumulated Other Comprehensive Income

The components of accumulated other comprehensive income at December 31 are as follows:

*Dollars in Thousands*

|  | 2004             | 2003          |
|--|------------------|---------------|
| Foreign Currency Translation Adjustments | \$ 20,254        | \$ 1,277      |
| Unrealized Losses on on Cash Flow Hedges | (500)            | (1,164)       |
| Total                                    | <u>\$ 19,754</u> | <u>\$ 113</u> |

## Revenue Recognition

The Company derives revenues from two principal sources: reagent (test kit) sales and IMMULITE instrument placements. The Company recognizes sales of test kits upon shipment and transfer of title to the customer. The Company believes that shipment and transfer of title, which occurs at time of shipment under the terms of its revenue transactions, to customers is the appropriate time to recognize revenue related to reagent test kits and instruments that are sold because in each case persuasive evidence of an arrangement exists in the form of a purchase order and invoice, delivery has occurred as the Company's shipping terms are FOB shipping point, the Company's price to the buyer is fixed as stated in the invoice, and collectibility is reasonably assured. As a result of these factors, once shipment and transfer of title occurs, the Company has fulfilled all of the requirements under its sales agreement with the customer and the related revenue for the test kits or sold instruments has been earned.

IMMULITE instruments are placed with customers under many different types of arrangements that generally fall into the following categories: sale, lease, reagent rental, and soft placement. The Company sells instruments directly to end-users, to third party leasing companies that lease the instruments to end-users, and to independent distributors that then resell the instruments to their customers. Instrument sales, which represent the smallest component of placements, are recognized upon shipment and transfer of title. The Company also places instruments under sales-type leases, which are recorded as revenue upon shipment in an amount equal to the present value of the future minimum lease payments to be received over the lease term.

Many instruments are placed other than by outright sale or sales-type lease. The Company enters into various types of lease arrangements with customers that generally provide for terms of three to five years and periodic rental payments. Revenue on leases is recognized on a pro rata basis over the term of the lease. When an instrument is placed on a reagent rental basis, the customer agrees to pay a mark-up on reagents, but is not charged for the instrument. The Company also places instruments at no charge to the customer (soft placement) subject to the customer's agreement to purchase a minimum amount of reagents. In reagent rentals and soft placements, the only revenue recognized is based on reagent shipments. Under operating lease, rental, and soft placements, DPC continues to own the instrument that is placed with the customer and the instruments come back to the Company at the end of the rental or lease period. These instruments are generally amortized on a straight-line basis over five years and maintenance costs are expensed as incurred. The Company also enters into service contracts with customers and recognizes service revenue over the related contract life (related costs are expensed as incurred).

Historically, the Company has rarely experienced sales returns. Therefore, no allowance has been provided.

## Research and Development

Research and development costs primarily include costs for employee salaries, utilities, depreciation and amortization expenses on machinery and equipment, and certain supplies that are incurred directly in the development of new products. Research and development costs are expensed as incurred.

## Stock Options

Stock options issued by the Company are accounted for in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25") as permitted by SFAS No. 123, "Accounting for Stock-Based Compensation." The Company follows the disclosure requirements of SFAS No. 123, as amended by SFAS No. 148, "Accounting for Stock-Based Compensation—Transition and Disclosure, an amendment of FASB Statement No. 123," which provides alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation, and amends the disclosure requirements of SFAS No. 123 to require prominent disclosures in both annual and interim financial statements about the method of accounting for stock-based employee compensation and the effect of the method used on reported results.

As permitted by SFAS No. 123, the Company has chosen to continue accounting for stock options at their intrinsic value. Accordingly, no compensation expense has been recognized for its stock option compensation plans as all options granted had an exercise price equal to the market value of the underlying common stock on the date of grant. Had the fair value method of accounting been applied to the Company's stock option plans, the tax-effected impact would be as follows:

Amounts in Thousands Except Per Share Data:

|                               | <u>2004</u>      | <u>2003</u>      | <u>2002</u>      |
|-------------------------------|------------------|------------------|------------------|
| Net Income:                   |                  |                  |                  |
| As Reported                   | \$ 61,735        | \$ 61,795        | \$ 47,313        |
| Pro Forma Expense, net of tax | <u>(2,988)</u>   | <u>(2,491)</u>   | <u>(2,692)</u>   |
| Pro Forma                     | <u>\$ 58,747</u> | <u>\$ 59,304</u> | <u>\$ 44,621</u> |
| Net Earnings Per Share        |                  |                  |                  |
| Basic:                        |                  |                  |                  |
| As Reported                   | \$ 2.12          | \$ 2.15          | \$ 1.66          |
| Pro Forma Adjustment          | <u>(0.10)</u>    | <u>(0.09)</u>    | <u>(0.09)</u>    |
| Pro Forma                     | <u>\$ 2.02</u>   | <u>\$ 2.06</u>   | <u>\$ 1.57</u>   |
| Diluted:                      |                  |                  |                  |
| As Reported                   | \$ 2.06          | \$ 2.08          | \$ 1.60          |
| Pro Forma Adjustment          | <u>(0.10)</u>    | <u>(0.08)</u>    | <u>(0.09)</u>    |
| Pro Forma                     | <u>\$ 1.96</u>   | <u>\$ 2.00</u>   | <u>\$ 1.51</u>   |

Weighted Average Assumptions for Pro Forma Disclosure:

|                         | <u>2004</u> | <u>2003</u> | <u>2002</u> |
|-------------------------|-------------|-------------|-------------|
| Expected option life    | 7.0 years   | 7.0 years   | 7.0 years   |
| Dividend yield          | 0.74%       | 0.65%       | 0.75%       |
| Volatility              | 30%         | 31%         | 36%         |
| Risk-free interest rate | 3.76%       | 3.49%       | 4.42%       |
| Forfeiture rate         | 7.6%        | 5.0%        | 5.0%        |

### Income Taxes

Deferred income taxes represent the income tax consequences on future years of differences between the income tax basis of assets and liabilities and their basis for financial reporting purposes multiplied by the applicable statutory income tax rate. Valuation allowances are established against deferred income tax assets if it is more likely than not that they will not be realized.

### New Accounting Pronouncements

In January 2003, the FASB issued FASB Interpretation No. ("FIN") 46, "Consolidation of Variable Interest Entities" ("FIN 46"). In December 2003, FIN 46 was replaced by FASB interpretation No. 46R "Consolidation of Variable Interest Entities." FIN 46R clarifies the application of Accounting Research Bulletin No. 51, "Consolidated Financial Statements," to certain entities in which equity investors do not have the characteristics of a controlling financial interest or do not have sufficient equity at risk for the entity to finance its activities without additional subordinate financial support from other parties. FIN 46R requires an enterprise to consolidate a variable interest entity if that enterprise will absorb a majority of the entity's expected losses, is entitled to receive a majority of the entity's expected residual returns, or both. FIN 46R was effective for special-purpose entities being evaluated under FIN 46R for consolidation on December 31, 2003 and was effective for all other entities being evaluated on March 31, 2004. The adoption of FIN 46R did not have a material impact on the Company's financial position or results of operations.

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123 (revised 2004) (FASB 123R), "Shared Based Payment." FASB 123R will require the Company to expense share-based payments, including employee stock options, based on their fair value. The Company is required to adopt the provisions of FASB 123R effective as of the beginning of its third quarter in 2005. FASB 123R provides for a modified retroactive application. The Company is currently evaluating the financial impact, including the available alternatives of adoption.

In 2004, the FASB issued Financial Accounting Standard ("FAS") No. 151 entitled inventory costs. This Statement amends the guidance in ARB No. 43, "Inventory Pricing," to clarify the accounting for abnormal amounts

of idle facility expense, freight handling costs, and wasted material (spoilage). The provisions of this Statement shall be effective for inventory costs incurred during fiscal years beginning after June 15, 2005. The Company is currently evaluating the impact of the adoption of FAS No. 151 on its financial position and results of operations.

In December 2004, the FASB issued FSP 109-1 "Application of FASB Statement No. 109 "Accounting for Income Taxes" to the tax deduction on qualified production activities provided by the American Jobs Creation Act of 2004." The FASB staff believes that the qualified production activities deduction provided by the American Jobs Creation Act of 2004 ("the AJCA") should be accounted for as a special deduction in accordance with FASB Statement No. 109 ("FAS 109"). The Company is in the process of determining the impact that FSP 109-1 and the AJCA will have on its operations.

In December 2004, the FASB issued FSP 109-2, "Accounting and Disclosure Guidance for the Foreign Earnings Repatriation Provision within the American Jobs Creation Act of 2004." See further discussion in Note 7.

## Reclassifications

Certain amounts have been reclassified in 2002 and 2003 to conform to the 2004 presentation.

## Note 2 – Inventories

Inventories by major categories are summarized as follows:

*Dollars in Thousands*

|                 | 2004             | 2003             |
|-----------------|------------------|------------------|
| Raw materials   | \$ 43,899        | \$ 39,145        |
| Work in process | 32,767           | 38,761           |
| Finished goods  | 16,562           | 8,596            |
|                 | <u>\$ 93,228</u> | <u>\$ 86,502</u> |

## Note 3 – Instruments

The non-current asset account "Instruments" on the accompanying balance sheet consists of IMMULITE instruments placed or leased to customers. The majority of instruments are placed with customers. Instruments are placed on either a reagent rental basis, in which the customer pays a mark-up on reagents but is not charged for the instrument, or on a soft placement basis, in which the customer does not pay for the instrument but agrees to purchase a minimum amount of reagents. The Company also leases instruments under operating-type leases and sells instruments under sales-type leases. Sales-type leases are recorded as revenue at the inception of the lease in an amount equal to the present value of the future minimum lease payments to be received over the lease term. The current portion of receivables from sales-type leases is included in Accounts Receivable and the long-term portion of these receivables is included in Instruments. Instruments are comprised of the following:

*Dollars in Thousands*

|                                 | 2004             | 2003             |
|---------------------------------|------------------|------------------|
| Placements and operating leases | \$ 227,434       | \$ 189,645       |
| Less accumulated amortization   | 150,956          | 119,009          |
| Net                             | <u>76,478</u>    | <u>70,636</u>    |
| Sales-type leases               | 7,234            | 6,594            |
| Less current portion            | 982              | 733              |
| Net                             | <u>6,252</u>     | <u>5,861</u>     |
| Total                           | <u>\$ 82,730</u> | <u>\$ 76,497</u> |

Instrument rental revenue was \$8,484,000 in 2004, \$8,072,000 in 2003, and \$5,479,000 in 2002. Placed instruments and instruments subject to operating leases are generally depreciated over five years. Future minimum lease payments receivable are as follows:

Dollars in Thousands

|  | Operating<br>Leases | Sales-Type<br>Leases |
|--|---------------------|----------------------|
| 2005   | \$ 2,965            | \$ 2,640             |
| 2006   | 1,883               | 2,101                |
| 2007   | 1,342               | 1,620                |
| 2008   | 786                 | 1,038                |
| 2009   | 204                 | 543                  |
| Thereafter   | -                   | -                    |
| Total  | <u>\$ 7,180</u>     | <u>7,942</u>         |
| Less amounts representing interest                 |                     | <u>708</u>           |
| Present value of minimum lease payments receivable |                     | <u>\$ 7,234</u>      |

Future minimum lease payments receivable for operating leases do not include instruments placed on a reagent rental basis, where the customer agrees to pay a mark-up on reagents but is not charged for the instrument or instruments placed at no charge to the customer (soft placement) subject to the customer's agreement to purchase a minimum amount of reagents. In reagent rentals and soft placements, the only revenue recognized is based on reagent shipments.

#### Note 4 – Investment in Affiliated Companies

The Company has equity interests in four non-consolidated foreign affiliates. The Company accounts for these interests using the equity method. The affiliates distribute the Company's products in their respective countries. The countries and the Company's ownership interest are as follows as of December 31, 2004: Portugal, 47.5%; Italy, 45%; Greece, 50% and Croatia, 50%. During 2004, the Company increased its equity interest in its Portuguese affiliate from 45% to 47.5% by purchasing an additional 2.5% of the outstanding shares for \$219,000.

The Company had sales to its non-consolidated foreign affiliates of \$32,867,000 in 2004, \$29,931,000 in 2003, and \$30,804,000 in 2002, including sales to Italy of \$26,916,000 in 2004, \$27,957,000 in 2003, and \$23,306,000 in 2002.

The Company also has a 10% equity interest in Lumigen Inc., a domestic affiliate. The Company purchases chemical compounds from Lumigen. The Company accounts for this interest using the equity method because the Company has the ability to exert significant influence as a result of its representation on Lumigen's Board of Directors and because the Company's purchases of chemical compounds from Lumigen are significant to Lumigen. The purchase of the chemical compounds from Lumigen is included in inventory and cost of sales. All material intercompany transactions have been eliminated.

The following represents condensed financial information for all of the Company's investments in its non-consolidated affiliated companies and the results of their operations.

*Dollars in Thousands*

|  | 2004              | 2003              | 2002              |
|--|-------------------|-------------------|-------------------|
| Current assets                             | \$ 104,777        | \$ 76,839         | \$ 62,933         |
| Property and other assets                  | 66,584            | 63,770            | 54,238            |
| Total assets                               | <u>\$ 171,361</u> | <u>\$ 140,609</u> | <u>\$ 117,171</u> |
| Current liabilities                        | \$ 66,783         | \$ 54,510         | \$ 45,425         |
| Non-current liabilities                    | 1,003             | 610               | 492               |
| Shareholders' equity                       | 103,575           | 85,489            | 71,254            |
| Total liabilities and shareholders' equity | <u>\$ 171,361</u> | <u>\$ 140,609</u> | <u>\$ 117,171</u> |
| Sales                                      | <u>\$ 129,660</u> | <u>\$ 110,680</u> | <u>\$ 87,460</u>  |
| Net income                                 | <u>\$ 27,367</u>  | <u>\$ 20,305</u>  | <u>\$ 14,711</u>  |

## **Note 5 – Notes Payable**

Notes payable consist of borrowings by certain of the Company's foreign subsidiaries (some guaranteed by Diagnostic Products Corporation) that are payable in the subsidiaries' local currency. The notes, translated into U.S. Dollars, are summarized as follows:

*Dollars in Thousands*

|  | 2004            | 2003          |
|--|-----------------|---------------|
| Variable rate notes payable to a bank in Germany, at an average interest rate of approximately 3%, payable through 2006. | \$ 8,757        | \$ 10,926     |
| Fixed rate note payable to a bank in France, at an average interest rate of approximately 5%, payable through 2007.      | 3,833           | 5,818         |
| Variable rate note payable to a bank in Spain, at an average interest rate of approximately 4%, payable through 2005.    | 332             | 1,894         |
| Variable rate note payable to a bank in Sweden, at an average interest rate of approximately 3%, payable through 2005.   | 62              | 718           |
| Fixed rate note payable to a bank in Netherlands, at an average interest rate of approximately 7%, payable through 2005. | 7               | 13            |
| Total  | <u>12,991</u>   | <u>19,369</u> |
| Less current portion   | 4,145           | 19,369        |
| Long-term portion  | <u>\$ 8,846</u> | <u>\$ -</u>   |

Aggregate future maturities of the debt outstanding at December 31, 2004 are \$4,145,000, \$8,283,000 and \$563,000 in 2005, 2006 and 2007, respectively. The Company pledged certain of its assets, principally buildings, land and equipment for approximately \$13 million of these borrowings at December 31, 2004.

The Company also has a line of credit with a bank, under which it may borrow up to \$20 million, which matures in July of 2005. There were no borrowings or standby letters of credit outstanding at December 31, 2004 or 2003 under the line of credit.

## **Note 6 – Employee Benefit Plans**

The Company has a defined contribution money purchase pension plan, the Diagnostic Products Corporation Retirement Plan (the "Plan"), covering substantially all U.S. employees over 21 years of age. The Plan offers three primary benefits to employees: a money purchase pension, a profit-sharing plan, and a salary deferral plan under the provisions of Section 401(k) of the Internal Revenue Code.

Contributions under the money purchase pension are made annually in an amount equal to 10% of the compensation of all participants for such year.

Contributions related to the pension benefit were \$6,108,000 for 2004, \$5,935,000 for 2003, and \$5,201,000 for 2002. Contributions related to the profit-sharing component for any year are made at the discretion of the Board of Directors of the Company, but cannot exceed 15% of the compensation of all participants for such year. The Company made no contributions to the profit-sharing component for 2004, while contributing \$900,000 for 2003 and \$1,001,000 for 2002. Contributions under the 401(k) salary deferral are at the option of the employee in percentage increments of the employee's salary not to exceed the maximum allowable under Federal law. The Company matches these contributions at a rate of 50 percent of the first \$1,000 of compensation contributed by the employee. The Company contributed 401(k) employer matches of \$572,000 for 2004, \$516,000 for 2003, and \$489,000 for 2002.

## Note 7 – Income Taxes

Income before income taxes is summarized as follows:

*Dollars in Thousands*

|          | 2004             | 2003             | 2002             |
|----------|------------------|------------------|------------------|
| Domestic | \$ 36,688        | \$ 50,665        | \$ 47,317        |
| Foreign  | 51,317           | 37,771           | 20,675           |
| Total    | <u>\$ 88,005</u> | <u>\$ 88,436</u> | <u>\$ 67,992</u> |

The provision for income taxes is summarized as follows:

*Dollars in Thousands*

|               | 2004             | 2003             | 2002             |
|---------------|------------------|------------------|------------------|
| Current       |                  |                  |                  |
| Federal       | \$ 3,659         | \$ 11,586        | \$ 11,841        |
| State         | 3,185            | 1,056            | (133)            |
| Foreign       | 11,389           | 11,825           | 9,939            |
|               | <u>18,233</u>    | <u>24,467</u>    | <u>21,647</u>    |
| Deferred      |                  |                  |                  |
| United States | 2,719            | 1,285            | 1,307            |
| Foreign       | 4,543            | 528              | (1,876)          |
|               | <u>7,262</u>     | <u>1,813</u>     | <u>(569)</u>     |
| Total         | <u>\$ 25,495</u> | <u>\$ 26,280</u> | <u>\$ 21,078</u> |

Current deferred income tax assets at December 31, 2004 include \$282,000 and \$499,000 at December 31, 2004 and 2003, respectively, related to the income tax benefits of unrealized losses on forward exchange contracts, which are included as a component of other comprehensive income.

Temporary differences comprising the net deferred taxes shown on the consolidated balance sheets are as follows:

Dollars in Thousands

|  | 2004              | 2003            |
|--|-------------------|-----------------|
| Inventory  | \$ (1,487)        | \$ (1,071)      |
| Depreciation and amortization                                  | (4,958)           | (688)           |
| Intercompany profit in ending inventory elimination            | 2,251             | 1,765           |
| Tax benefit of unrealized losses on forward exchange contracts | 282               | 499             |
| Accruals on foreign contingencies                              | 1,611             | 1,477           |
| Research and development credit carry-forwards                 | 3,043             | 3,102           |
| State net operating loss carry-forwards                        | 4,323             | 2,923           |
| Other  | 490               | 3,245           |
| Valuation allowance  | (7,366)           | (5,584)         |
| Total deferred tax (liability) asset                           | <u>\$ (1,811)</u> | <u>\$ 5,668</u> |

State net operating loss carry-forwards totaled \$48,036,000 as of December 31, 2004, and \$32,484,000 as of December 31, 2003. Such loss carry-forwards expire in accordance with provisions of applicable tax laws. These losses begin to expire during the years 2008 through 2011. Research and development tax credits total \$3,043,000 as of December 31, 2004 and \$3,102,000 as of December 31, 2003. These credits begin to expire during the years 2005 through 2011. The Company maintains a valuation allowance for the entire net operating loss and research and development tax credit carry-forward as utilization of these losses and credits because the Company does not believe that recoverability is more likely than not.

Reconciliation between the provision for income taxes computed by applying the federal statutory tax rate to income before income taxes and the actual provision for income taxes is as follows:

Dollars in Thousands

|  | 2004          | %            | 2003          | %            | 2002          | %            |
|--|---------------|--------------|---------------|--------------|---------------|--------------|
| Provision for income taxes at statutory rate                       | \$ 30,802     | 35.0%        | \$ 30,953     | 35.0%        | \$ 23,797     | 35.0%        |
| Foreign income subject to tax at other than federal statutory rate | (2,029)       | -2.3%        | (867)         | -1.0%        | 1,154         | 1.7%         |
| State income taxes, net of federal benefit                         | 647           | 0.7%         | 1,072         | 1.2%         | 6             | 0.0%         |
| Extra Territorial Income/Foreign Sales Corp benefit                | (2,037)       | -2.3%        | (2,457)       | -2.8%        | (1,892)       | -2.8%        |
| Research and development tax credits                               | (1,361)       | -1.5%        | (1,281)       | -1.4%        | (1,236)       | -1.8%        |
| Equity in income of affiliates                                     | (2,957)       | -3.3%        | (2,122)       | -2.4%        | (1,334)       | -2.0%        |
| Valuation allowance  | 1,782         | 2.0%         | (441)         | -0.5%        | -             | 0.0%         |
| Other  | 648           | 0.7%         | 1,423         | 1.6%         | 583           | 0.9%         |
| Total provision for income taxes                                   | <u>25,495</u> | <u>29.0%</u> | <u>26,280</u> | <u>29.7%</u> | <u>21,078</u> | <u>31.0%</u> |

The Company is routinely involved in federal and state income tax audits. To provide for potential tax exposures, the Company maintains an allowance for tax contingencies which management believes is adequate.

The Company's cumulative equity in undistributed earnings of consolidated foreign subsidiaries at December 31, 2004 is \$124,387,000. The Company's cumulative equity in undistributed earnings of unconsolidated foreign affiliates at December 31, 2004 is \$30,369,000. At this time it is not practical to calculate the income taxes payable on undistributed earnings of unconsolidated foreign affiliates.

On October 22, 2004, the American Jobs Creation Act ("AJCA") was signed into law. The AJCA includes a deduction of 85% of certain foreign earnings that are repatriated, as defined in the AJCA. The Company may elect to apply this provision to qualifying earnings repatriations in either fiscal year 2004 or in fiscal year 2005. Any such repatriation under the AJCA must occur by December 31, 2005. In December 2004, the FASB issued FASB Staff Position No. 109-2 ("FSP 109-2"), "Accounting and Disclosure Guidance for the Foreign Repatriation Provision within the American Jobs Creation Act of 2004," which provides guidance under SFAS No. 109 with respect to recording the potential impact of the repatriation provisions of the AJCA on a company's income tax expense and deferred tax liability. FSP 109-2 states that a company is allowed time beyond the financial reporting period of enactment to evaluate the effect of the AJCA on its plan for reinvestment or repatriation of foreign earnings for purposes of applying SFAS No. 109. No provision has been made for the United States federal and state, or foreign taxes that may result from future remittances of undistributed earnings of foreign subsidiaries. The Company is currently reviewing the provisions of the AJCA and at this time the related range of income tax effects cannot be

reasonably estimated. Whether DPC will ultimately take advantage of this provision depends on a number of factors, including reviewing future Congressional guidance before making a decision. The Company expects to complete its evaluation no later than September 30, 2005.

## **Note 8 – Commitments and Contingent Liabilities**

In the fourth quarter of fiscal year 2002, the Company discovered internally that certain senior managers and other employees of its Chinese subsidiary had made certain improper payments that may have violated foreign and U.S. laws. Beginning in the early 1990s, the Chinese subsidiary made cash payments and provided in kind benefits to hospital and laboratory customers of the Chinese subsidiary and to employees of such customers. Because certain of the customers were state owned enterprises and the payments may have been for the purpose, or may have had the effect, of causing those customers to purchase products from the Chinese subsidiary, these payments and benefits may have violated the U.S. Foreign Corrupt Practices Act as well as certain domestic Chinese laws. In addition, the deduction of these payments and benefits by the subsidiary on its tax returns may have been improper under the Chinese tax law, resulting in underpayments of Chinese taxes.

An independent investigation by the Company's audit committee concluded that no current members of the Company's senior management knew of or were involved in the provision of the payments and benefits. The Company has made changes in the management of the Chinese subsidiary, including replacement of the senior managers involved, and has implemented procedures and controls to address these issues and to promote compliance with applicable laws. The Company voluntarily disclosed these payment issues to the Securities and Exchange Commission (SEC) and the Department of Justice (DOJ) in the first quarter of 2003 and has been cooperating fully with these agencies in their investigations since that time.

The Company's discussions with both the SEC and the DOJ are at fairly advanced stages and include proposals that the Company pay an aggregate of approximately \$4.8 million to those agencies, consisting of \$2.0 million in fines and approximately \$2.8 million in disgorgement of profits and related interest charges. The proposals being discussed also include changes to the Company's compliance programs, independent monitoring of and reporting on those programs for up to 36 months, entry of a cease and desist order and either a deferred prosecution agreement or a plea by the Company's Chinese subsidiary. Any settlement recommended by the staff of the SEC would be subject to approval by the Commission and any deferred prosecution or plea agreement would be subject to court approval. In the fourth quarter of 2002, the Company accrued \$1.5 million for actual and estimated costs to resolve this matter. In the third quarter of 2004, the Company accrued an additional \$1.0 million based on its revised estimates of costs that will be paid to the U.S. Government to resolve the matter. In the fourth quarter of 2004, the Company accrued an additional \$2.4 million, including \$750,000 in interest, based on the proposed settlements with the SEC and the DOJ. As of December 31, 2004, \$4.8 million remained in the accrual. In addition, the Company recorded a charge of \$1.4 million to its 2002 fourth quarter tax provision related to the non-deductibility of the payments in China. During the third quarter of 2003, the Company recorded an additional charge of \$0.9 million to its income tax provision for this and other Chinese tax-related matters. Legal expenses relating to this matter of approximately \$884,000 and \$1,712,000 have been incurred and charged to general and administrative expense during the years ended December 31, 2003 and 2004, respectively. It is anticipated that legal fees for issues related to China will decrease in 2005. The termination of the improper payments in China has had and may continue to have a significant adverse effect on future operations in China because such termination could negatively influence a significant number of the Chinese subsidiary's customers' decisions as to whether to continue to do business with that subsidiary. For the year ended December 31, 2004, the Chinese subsidiary had sales of \$8.2 million versus sales of \$9.8 million in 2003.

In February 2004, the Company was informed by the U.S. Food and Drug Administration (FDA) that, based on inspectional findings that included data integrity and procedural issues related solely to the Company's application for the IMMULITE Chagas test, the Company was subject to the FDA's Application Integrity Policy ("AIP"). The FDA suspended its review of all applications submitted by the Company and will not review any future applications until the FDA determines that the Company has resolved these issues, although studies to support future applications can be conducted while on AIP.

To address the AIP issues, the Company was audited by a third party, whose report has been submitted to the FDA. The Company also developed and implemented a corrective action plan that was submitted to the FDA. The Company has requested the FDA to take any action necessary to remove it from the AIP, which may include an inspection by the FDA. The Company believes that the AIP issues will be resolved with the FDA and hopes that to occur in the next few months. The FDA's application of the AIP to DPC does not restrict DPC from introducing new tests outside of the United States. However, the Company's inability to introduce new tests in the United States during the pendency of the AIP may have a negative impact on its future sales and profits.

In late July 2004, the Company was served with a subpoena requiring it to produce to the Federal grand jury for the Central District of California, documents relating to trading in the Company's securities and the exercise of options by officers, directors and employees of the Company between December 30, 2003 and April 1, 2004. The subpoena also seeks all documents relating to the FDA's review of the Company's diagnostic test to detect Chagas and any audits or reviews by the FDA between 2000 and the present relating to the Company's products. Finally, the subpoena seeks the personnel file of a former Company employee. The Company is cooperating with the United States Attorney and the SEC regarding these matters. An independent committee of the Board of Directors has conducted an investigation of the trading issues and has presented its findings and conclusions to the United States Attorney and the SEC. Although it is in the early stages of the process, management believes the ultimate resolution of this matter will not have a material financial impact to the Company.

The Company's Brazilian subsidiary is a participant along with various other companies in a number of lawsuits against the Brazilian Government claiming unlawful taxation. Historically the companies involved in these suits have had limited success in having these taxes over turned. The Company has also purchased unused tax credits for approximately \$1.0 million from an unrelated company. However due to uncertainty related to the Company's ability to use these credits against its tax liabilities, it has fully reserved against the cost of these credits. These court cases typically take many years to be decided and the Company estimates what its most likely loss outcome will be based on the merits of the individual cases and advice of outside counsel. As of December 31, 2004, the Company has accrued for the amounts it believes it will have to pay. In the suit that involves the majority of the disputed taxes, in this case sales taxes, if the courts were to rule against the Company in all actions, it would create an additional liability of \$1.0 million.

The Company has a non-cancelable operating lease for a portion of its Los Angeles manufacturing facility with a partnership comprised of persons who are executive officers, directors, and/or shareholders of the Company. The agreement is on a month-to-month basis until new terms are agreed upon between the Company and the partnership. The Company paid approximately \$1,035,000 for 2004 and 2003 and \$966,000 in 2002, under the facility lease agreement.

Future minimum lease commitments of non-related party operating leases as of December 31, 2004 are as follows:

*Dollars in Thousands*

|            |    |               |
|------------|----|---------------|
| 2005       | \$ | 7,807         |
| 2006       |    | 4,376         |
| 2007       |    | 2,835         |
| 2008       |    | 1,938         |
| 2009       |    | 1,079         |
| Thereafter |    | 1,274         |
| Total      | \$ | <u>19,309</u> |

Aggregate rental expense under operating leases approximated \$4,442,000 in 2004, \$4,405,000 in 2003 and \$4,965,000 in 2002.

## Note 9 – Earnings per Share

The following table is a reconciliation of the weighted-average shares used in the computation of basic and diluted Earnings Per Share (EPS) for the income statements presented herein.

Net income as presented in the consolidated income statement is used as the numerator in the EPS calculation for both the basic and diluted computations.

*Shares in Thousands*

|                                   | 2004          | 2003          | 2002          |
|-----------------------------------|---------------|---------------|---------------|
| Basic                             | <u>29,082</u> | <u>28,731</u> | <u>28,487</u> |
| Assumed exercise of stock options | <u>830</u>    | <u>948</u>    | <u>1,141</u>  |
| Diluted                           | <u>29,912</u> | <u>29,679</u> | <u>29,628</u> |

Stock options to purchase 153,984 shares of common stock in 2004, 256,260 shares of common stock in 2003 and 256,000 shares in 2002 were outstanding but not included in the computation of diluted earnings per common share because the option price was greater than the average market price of the common shares.

## Note 10 – Stock Option Plans

Under the Company's stock option plans, all of which have been approved by the Company's shareholders, incentive stock options may be granted and are exercisable at prices not less than 100% of the fair market value on the date of the grant (110% with respect to optionees who are 10% or more shareholders of the Company). Additionally under the plans, non-qualified stock options may be granted and are exercisable at prices not less than 85% of fair market value at the date of grant. Options generally become exercisable after one year, in installments (generally over 3 to 9 years), and may be exercised on a cumulative basis at any time before expiration. Options expire no later than ten years from the date of grant.

The following table provides the stock option activity for the three years ended December 31, 2004.

|  | Number<br>of<br>Shares  | Weighted<br>Average<br>Exercise Price | Weighted<br>Average<br>Fair Value |
|--|-------------------------|---------------------------------------|-----------------------------------|
| Options outstanding, January 1, 2002 (547,383 exercisable)   | 2,492,018               | \$ 18.22                              |                                   |
| Granted  | 179,000                 | 39.26                                 | \$ 16.70                          |
| Exercised  | (260,609)               | 15.17                                 |                                   |
| Canceled   | (18,600)                | 21.96                                 |                                   |
| Options outstanding, December 31, 2002 (742,742 exercisable) | <u>2,391,809</u>        | 20.10                                 |                                   |
| Granted  | 209,000                 | 39.81                                 | 14.83                             |
| Exercised  | (304,190)               | 14.05                                 |                                   |
| Canceled   | (41,800)                | 24.07                                 |                                   |
| Options outstanding, December 31, 2003 (822,885 exercisable) | <u>2,254,819</u>        | 22.68                                 |                                   |
| Granted  | 264,000                 | 44.40                                 | 14.86                             |
| Exercised  | (320,827)               | 17.43                                 |                                   |
| Canceled   | (65,000)                | 23.28                                 |                                   |
| Options outstanding, December 31, 2004 (899,993 exercisable) | <u><u>2,132,992</u></u> |                                       |                                   |

The following table summarizes information about stock options outstanding at December 31, 2004:

| Range of<br>Exercise<br>Prices | Number<br>Outstanding<br>at 12/31/04 | Weighted<br>Average<br>Remaining<br>Life | Weighted<br>Average<br>Exercise<br>Price | Number<br>Exercisable<br>at 12/31/04 | Weighted<br>Average<br>Exercise<br>Price |
|--------------------------------|--------------------------------------|--|--|--------------------------------------|--|
| \$ 0.00-9.99                   | -                                    | 0.0 years                                | \$ -                                     | -                                    | \$ -                                     |
| \$10.00-19.99                  | 1,036,824                            | 3.6 years                                | \$ 13.93                                 | 523,823                              | \$ 14.41                                 |
| \$20.00-29.99                  | 171,568                              | 6.0 years                                | \$ 24.00                                 | 87,967                               | \$ 23.98                                 |
| \$30.00-39.99                  | 372,000                              | 7.3 years                                | \$ 35.74                                 | 149,602                              | \$ 35.07                                 |
| \$40.00-49.99                  | 545,600                              | 8.3 years                                | \$ 43.13                                 | 138,601                              | \$ 41.81                                 |
| \$50.00-59.99                  | 7,000                                | 10 years                                 | \$ 52.10                                 | -                                    | \$ -                                     |
|                                | <u><u>2,132,992</u></u>              |  |  | <u><u>899,993</u></u>                |  |

Pursuant to the plans, 2,132,992 shares of common stock are reserved for issuance upon the exercise of outstanding options. In addition, the Company has 1,184,800 options available for future grant.

## NOTE 11 - Segment and Product Line Information

The Company considers its manufactured instruments and medical immunodiagnostic test kits to be one operating segment as defined under SFAS No. 131, "Disclosures about Segments of an Enterprise and Related Information," as

the kits are required to run the instruments and utilize similar technology and instrument manufacturing processes. The Company manufactures its instruments and kits principally at facilities located in the United States and the United Kingdom. Kits and instruments are sold to hospitals, medical centers, clinics, physicians, and other clinical laboratories throughout the world through a network of distributors, including consolidated distributors located in the United Kingdom, Germany, Czech Republic, Poland, Slovenia, Slovakia, Croatia, Spain, The Netherlands, Belgium, Luxemburg, Sweden, Denmark, Norway, Finland, Latvia, Lithuania, Estonia, France, Australia, New Zealand, China, Brazil, Costa Rica, Venezuela, Uruguay, Bolivia, Honduras, Guatemala and Panama.

The Company sells its instruments and immunodiagnostic test kits under several product lines. Product line sales information is as follows:

*Dollars in Thousands*

|                              | <u>2004</u>       | <u>2003</u>       | <u>2002</u>       |
|------------------------------|-------------------|-------------------|-------------------|
| Sales:                       |                   |                   |                   |
| IMMULITE (including service) | \$ 404,856        | \$ 337,957        | \$ 276,776        |
| Radioimmunoassay ("RIA")     | 24,136            | 26,688            | 29,859            |
| Other                        | 14,181            | 16,741            | 17,452            |
| Total                        | <u>\$ 443,173</u> | <u>\$ 381,386</u> | <u>\$ 324,087</u> |

The Company is organized and managed by geographic area. Transactions between geographic segments are accounted for as normal sales for internal reporting and management purposes with all intercompany amounts eliminated in consolidation. Sales are attributed to geographic area based on the location from which the instrument or kit is shipped to the customer. Information reviewed by the Company's chief operating decision maker on significant geographic segments, as defined under SFAS No. 131, is prepared on the same basis as the consolidated financial statements and is provided in the following tables. Items listed in "Other" represent those geographic locations that are individually insignificant.

## Segment and Product Line Footnote

December 31, 2004

| <i>Dollars in Thousands</i>      | Euro/DPC      |                          | DPC                     | DPC                      | Other     | Less:                    | Total      |
|----------------------------------|---------------|--------------------------|-------------------------|--------------------------|-----------|--------------------------|------------|
|                                  | United States | Limited (United Kingdom) | Biermann (German Group) | Medlab (Brazilian Group) |           | Intersegment Elimination |            |
| Sales                            | \$ 278,056    | \$ 90,017                | \$ 58,089               | \$ 39,703                | \$ 97,803 | \$ (120,495)             | \$ 443,173 |
| Operating expenses               | 106,340       | 12,243                   | 15,236                  | 10,325                   | 26,547    |                          | 170,691    |
| Depreciation and amortization    | 13,042        | 4,382                    | 11,416                  | 5,452                    | 9,314     |                          | 43,606     |
| Equity in (income) of affiliates | (8,451)       |                          |                         |                          |           |                          | (8,451)    |
| Interest income (expense), net   | 3,392         | 1,107                    | (1,256)                 | (1,609)                  | (734)     |                          | 900        |
| Other income (expense), net      | 125           | 287                      | (126)                   | (571)                    | (198)     |                          | (483)      |
| Minority interest                |               |                          |                         | 273                      |           | 502                      | 775        |
| Provision for income taxes       | 9,947         | 9,210                    | 873                     | 907                      | 4,558     |                          | 25,495     |
| Net income                       | 26,741        | 21,196                   | 2,103                   | 1,762                    | 10,435    | (502)                    | 61,735     |
| Segment assets:                  |               |                          |                         |                          |           |                          |            |
| Long-lived assets                | 201,854       | 33,178                   | 37,375                  | 16,495                   | 35,595    | (32,390)                 | 292,107    |
| Total assets                     | 590,052       | 95,443                   | 59,940                  | 36,737                   | 97,368    | (304,359)                | 575,181    |
| Capital expenditures             | 35,214        | 9,620                    | 1,303                   | 3,404                    | 779       |                          | 50,320     |

December 31, 2003

| <i>Dollars in Thousands</i>      | Euro/DPC      |                          | DPC                     | DPC                      | Other     | Less:                    | Total      |
|----------------------------------|---------------|--------------------------|-------------------------|--------------------------|-----------|--------------------------|------------|
|                                  | United States | Limited (United Kingdom) | Biermann (German Group) | Medlab (Brazilian Group) |           | Intersegment Elimination |            |
| Sales                            | \$ 242,963    | \$ 66,601                | \$ 52,529               | \$ 31,937                | \$ 86,522 | \$ (99,166)              | \$ 381,386 |
| Operating expenses               | 81,183        | 10,563                   | 11,989                  | 8,493                    | 23,249    |                          | 135,477    |
| Depreciation and amortization    | 8,289         | 3,921                    | 10,143                  | 3,632                    | 9,484     |                          | 35,469     |
| Equity in (income) of affiliates | (6,064)       |                          |                         |                          |           |                          | (6,064)    |
| Interest income (expense), net   | 4,025         | 306                      | (1,224)                 | (1,366)                  | (914)     |                          | 827        |
| Other income (expense), net      | (2,476)       | 57                       | 374                     | (941)                    | 2,986     |                          | -          |
| Minority interest                |               |                          |                         | 187                      |           | 174                      | 361        |
| Provision for income taxes       | 13,927        | 5,951                    | 1,159                   | 424                      | 4,819     |                          | 26,280     |
| Net income                       | 36,740        | 13,868                   | 2,086                   | 822                      | 8,453     | (174)                    | 61,795     |
| Segment assets:                  |               |                          |                         |                          |           |                          |            |
| Long-lived assets                | 152,270       | 23,724                   | 35,008                  | 12,883                   | 35,906    | (30,510)                 | 229,281    |
| Total assets                     | 485,289       | 64,538                   | 54,319                  | 28,845                   | 88,707    | (234,116)                | 487,582    |
| Capital expenditures             | 30,550        | 5,371                    | 461                     | 1,667                    | 3,916     |                          | 41,965     |

December 31, 2002

| <i>Dollars in Thousands</i>      | Euro/DPC      |                          | DPC                     | DPC                      | Other     | Less:                    | Total      |
|----------------------------------|---------------|--------------------------|-------------------------|--------------------------|-----------|--------------------------|------------|
|                                  | United States | Limited (United Kingdom) | Biermann (German Group) | Medlab (Brazilian Group) |           | Intersegment Elimination |            |
| Sales                            | \$ 227,369    | \$ 44,791                | \$ 40,632               | \$ 29,011                | \$ 70,756 | \$ (88,472)              | \$ 324,087 |
| Operating expenses               | 78,316        | 8,024                    | 9,469                   | 7,570                    | 17,591    |                          | 120,970    |
| Depreciation and amortization    | 11,964        | 3,499                    | 6,763                   | 3,230                    | 9,285     |                          | 34,741     |
| Equity in (income) of affiliates | (3,841)       |                          |                         |                          |           |                          | (3,841)    |
| Interest income (expense), net   | 3,415         | (207)                    | (1,158)                 | (1,280)                  | (1,027)   |                          | (257)      |
| Other income (expense), net      | 266           |                          | 1,146                   | (3,378)                  | 1,003     |                          | (963)      |
| Minority interest                |               |                          |                         | (120)                    |           | 519                      | 399        |
| Provision for income taxes       | (13,016)      | (4,088)                  | (413)                   | 467                      | (4,028)   |                          | (21,078)   |
| Net income                       | 34,302        | 9,468                    | 625                     | (906)                    | 3,305     | 519                      | 47,313     |
| Segment assets:                  |               |                          |                         |                          |           |                          |            |
| Long-lived assets                | 87,735        | 18,688                   | 32,995                  | 8,803                    | 23,881    |                          | 172,102    |
| Total assets                     | 416,758       | 44,958                   | 49,071                  | 21,055                   | 69,932    | (208,327)                | 393,447    |
| Capital expenditures             | 5,955         | 1,994                    | 853                     | 365                      | 3,301     |                          | 12,468     |

The Company's export sales to unaffiliated customers are summarized as follows:

Segment and Product Line Footnote

| <i>Dollars in Thousands</i> | Western  | South    | Other Exports | Total Exports |
|-----------------------------|----------|----------|---------------|---------------|
|                             | Europe   | America  |               |               |
| 2004                        | \$ 3,882 | \$ 7,577 | \$ 31,695     | \$ 43,154     |
| 2003                        | 4,380    | 7,683    | \$ 27,962     | \$ 40,025     |
| 2002                        | 4,358    | 6,529    | \$ 25,787     | \$ 36,674     |

## SUPPLEMENTARY FINANCIAL DATA

Unaudited quarterly financial information for the years ended December 31, 2004 and 2003 is summarized as follows:

| <i>Dollars in Thousands, Except Per Share Data</i> | Quarter Ended     |                  |                       |                      |                    |
|--|-------------------|------------------|-----------------------|----------------------|--------------------|
|  | March 31,<br>2004 | June 30,<br>2004 | September 30,<br>2004 | December 31,<br>2004 | Year Ended<br>2004 |
| Sales  | 106,083           | 110,468          | 108,963               | 117,659              | 443,173            |
| Gross profit                                       | 60,061            | 65,652           | 62,531                | 61,584               | 249,828            |
| Income taxes                                       | 6,602             | 8,011            | 6,573                 | 4,309                | 25,495             |
| Net income   | 15,457            | 18,619           | 16,517                | 11,142               | 61,735             |
| Earnings per share:                                |                   |                  |                       |                      |                    |
| Basic  | \$ 0.53           | \$ 0.64          | \$ 0.57               | \$ 0.38              | \$ 2.12            |
| Diluted  | \$ 0.52           | \$ 0.62          | \$ 0.55               | \$ 0.37              | \$ 2.06            |
| Weighted average shares outstanding:               |                   |                  |                       |                      |                    |
| Basic  | 28,972            | 29,059           | 29,120                | 29,181               | 29,082             |
| Diluted  | 29,944            | 29,866           | 29,853                | 30,016               | 29,912             |

|                                      | Quarter Ended     |                  |                       |                      |                    |
|--------------------------------------|-------------------|------------------|-----------------------|----------------------|--------------------|
|                                      | March 31,<br>2003 | June 30,<br>2003 | September 30,<br>2003 | December 31,<br>2003 | Year Ended<br>2003 |
| Sales                                | 86,880            | 95,951           | 93,737                | 104,818              | 381,386            |
| Gross profit                         | 50,324            | 55,987           | 52,402                | 58,309               | 217,022            |
| Income taxes                         | 5,155             | 6,843            | 6,988                 | 7,294                | 26,280             |
| Net income                           | 12,707            | 16,622           | 16,965                | 15,501               | 61,795             |
| Earnings per share:                  |                   |                  |                       |                      |                    |
| Basic                                | \$ 0.44           | \$ 0.58          | \$ 0.59               | \$ 0.54              | \$ 2.15            |
| Diluted                              | \$ 0.43           | \$ 0.56          | \$ 0.57               | \$ 0.52              | \$ 2.08            |
| Weighted average shares outstanding: |                   |                  |                       |                      |                    |
| Basic                                | 28,622            | 28,690           | 28,670                | 28,850               | 28,731             |
| Diluted                              | 29,544            | 29,659           | 29,697                | 29,804               | 29,679             |

### 2004 Fourth Quarter Items

During the year ended December 31, 2004, the Company recorded fourth quarter amounts of \$2.4 million (\$1.6 million in General and Administrative expense and \$750,000 in interest expense) to reflect a tentative settlement reached with the Department of Justice and the Securities and Exchange Commission regarding the Company's Chinese subsidiary, \$1.4 million to cost of sales for a homocysteine license to cover customer's historical purchases of the Company's homocysteine tests and \$1.0 million in inventory write downs related in part to discontinued products, in particular the microplate allergy line.

## 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.

### DIAGNOSTIC PRODUCTS CORPORATION

|   |   |                |
|---|---|----------------|
| <u>/s/ Michael Ziering</u><br>Michael Ziering | Chief Executive Officer and<br>Chairman of the Board<br>(Principal Executive Officer)<br>Director | March 16, 2005 |
|---|---|----------------|

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>TITLE</u>  | <u>DATE</u>    |
|---|---|----------------|
| <u>/s/ Michael Ziering</u><br>Michael Ziering         | Chief Executive Officer and<br>Chairman of the Board<br>(Principal Executive Officer)<br>Director | March 16, 2005 |
| <u>/s/ Sidney A. Aroesty</u><br>Sidney A. Aroesty     | President and<br>Chief Operating Officer<br>Director  | March 16, 2005 |
| <u>/s/ Maxwell H. Salter</u><br>Maxwell H. Salter     | Director  | March 16, 2005 |
| <u>/s/ James D. Watson</u><br>James D. Watson         | Director  | March 16, 2005 |
| <u>/s/ Frederick Frank</u><br>Frederick Frank         | Director  | March 16, 2005 |
| <u>/s/ Kenneth A. Merchant</u><br>Kenneth A. Merchant | Director  | March 16, 2005 |
| <u>/s/ John H. Reith</u><br>John H. Reith             | Director  | March 16, 2005 |
| <u>/s/ Ira Ziering</u><br>Ira Ziering                 | Senior Vice President<br>Director   | March 16, 2005 |
| <u>/s/ James L. Brill</u><br>James L. Brill           | Vice President<br>Finance (Principal<br>Financial and Accounting<br>Officer)                      | March 16, 2005 |

## EXHIBIT INDEX

- 3.1 Amended and Restated Articles of Incorporation (2)
- 3.2 Bylaws (9)
- 4.1 Stock Certificate (3)
- \*10.1 Form of Indemnification Agreement with Officers and Directors (1)
- \*10.2 1990 Stock Option Plan as amended (5)
- 10.3 Standard Industrial Lease with 5700 West 96th Street, general partnership, dated February 18, 1991 (4) and second addendum dated April 1, 2002 (7)
- \*10.4 1997 Stock Option Plan as amended (6) and form of Non-Qualified and Incentive Stock Option Agreements (8)
- 10.5 First Amendment to the Settlement Agreement effective as of October 1, 2003 (rights regarding Immulite chemical compounds) Note: Portions of this exhibit have been omitted pursuant to a request for confidential treatment (8)
- 21 Subsidiaries of Registrant
- 23 Report of Independent Registered Public Accounting Firm
- 31.1 Certificate of Chief Executive Officer
- 31.2 Certificate of Chief Financial Officer
- 32.1 Section 906 Officers' Certification

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\* Management contracts, compensation plans, or arrangements

- (1) Incorporated by reference to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 1988. (File No. 1-9957)
- (2) Incorporated by reference to Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2001. (File No. 1-9957)
- (3) Incorporated by reference to Registrant's Annual Report on Form 10-K for the year ended December 31, 1988. (File No. 1-9957)
- (4) Incorporated by reference to Registrant's Annual Report on Form 10-K for the year ended December 31, 1990. (File No. 1-9957)
- (5) Incorporated by reference to Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 1999. (File No. 1-9957)
- (6) Incorporated by reference to Registrant's registration statement on Form S-8 (file no. 333-60690) filed on May 11, 2001.
- (7) Incorporated by reference to registrant's quarterly report on Form 10-Q for the quarter ended March 31, 2002. (File No. 1-9957)
- (8) Incorporated by reference to Registrant's quarterly report on Form 10-Q for the quarter ended September 30, 2004 (File No. 1-9957)
- (9) Incorporated by reference to Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2004 (File No. 1-9957)

## EXHIBIT 31.1

### CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Michael Ziering, certify that:

1. I have reviewed this report on Form 10-K of Diagnostic Products Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15e and 15d-15e) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of the internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated March 16, 2005

/s/ Michael Ziering

Michael Ziering, Chief Executive Officer

## EXHIBIT 31.2

### CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, James L. Brill, certify that:

1. I have reviewed this report on Form 10-K of Diagnostic Products Corporation;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15e and 15d-15e) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:
  - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures as of the end of the period covered by this report based on such evaluation; and
  - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of the internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize, and report financial information; and
  - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated March 16, 2005

/s/ James L. Brill

James L. Brill, Chief Financial Officer

## EXHIBIT 32.1

### OFFICERS' CERTIFICATION

Each of the undersigned hereby certifies in his capacity as an officer of Diagnostic Products Corporation ("DPC") that the Annual Report of DPC on Form 10-K for the year ended December 31, 2004, fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934 and that the information contained in such report fairly presents, in all material respects, the financial condition of DPC at the end of such period and the results of its operations for such period.

Dated March 16, 2005

/S/ Michael Ziering

Michael Ziering, Chief Executive Officer

/S/ James L. Brill

James L. Brill, Chief Financial Officer

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## CORPORATE OFFICERS

**Michael Ziering**  
Chairman  
Chief Executive Officer

**Sidney A. Aroesty**  
President  
Chief Operating Officer

**Douglas Olson, Ph.D.**  
Chief Scientific Officer  
President, DPC  
Instrument Systems  
Division

**Marilyn Ziering**  
Senior Vice President

**James L. Brill**  
Vice President,  
Finance,  
Chief Financial Officer

**Ira Ziering**  
Senior Vice President,  
Business and Legal

**Robert Di Tullio**  
Vice President,  
Regulatory Affairs and  
Quality Systems

**Kathy J. Maugh**  
Vice President,  
Quality Assurance and  
Technical Services

**Nico Arnold**  
Vice President,  
Sales and Marketing

## BOARD OF DIRECTORS

**Michael Ziering**  
Chairman  
Chief Executive Officer

**Sidney A. Aroesty**  
President  
Chief Operating Officer

**Frederick Frank (1)(2)**  
Vice Chairman,  
Lehman Brothers Inc.,  
New York, NY

**Kenneth A. Merchant**  
(1)(2)(3)  
Professor of Accounting,  
University of Southern  
California  
Los Angeles, CA

**John H. Reid (1)(3)**  
President,  
The Reith Company,  
Pasadena, CA

**Maxwell H. Salter (2)**  
Chairman and  
Chief Executive Officer  
of Benos,  
Los Angeles, CA

**James D. Watson, Ph.D. (3)**  
Nobel Laureate,  
Chancellor of Cold Spring  
Harbor Laboratory,  
Cold Spring Harbor, NY

**Ira Ziering**  
Senior Vice President,  
Business and Legal

1. Audit Committee
2. Compensation Committee
3. Nominating/  
Governance Committee

## COMPANY INFORMATION

We maintain a direct mailing list for shareholders and other interested persons who desire to receive annual and quarterly financial information. If you would like your name added to the list, please direct your request to the Vice President, Finance at the Corporate Office.

Company information, including news releases and SEC filings, is also available on our website at [www.dpcweb.com](http://www.dpcweb.com).

## TRANSFER AGENT AND REGISTRAR

Mellon Investor Services  
400 South Hope Street  
Los Angeles, CA 90071

## INDEPENDENT AUDITORS

Deloitte & Touche LLP  
350 South Grand Avenue  
Los Angeles, CA 90017-3462

## FORM 10-K

A copy of the Company's Annual Report on Form 10-K as filed with the Securities and Exchange Commission is available without charge upon request. Requests should be directed to the Vice President, Finance at the Corporate Office.

## STOCK EXCHANGE

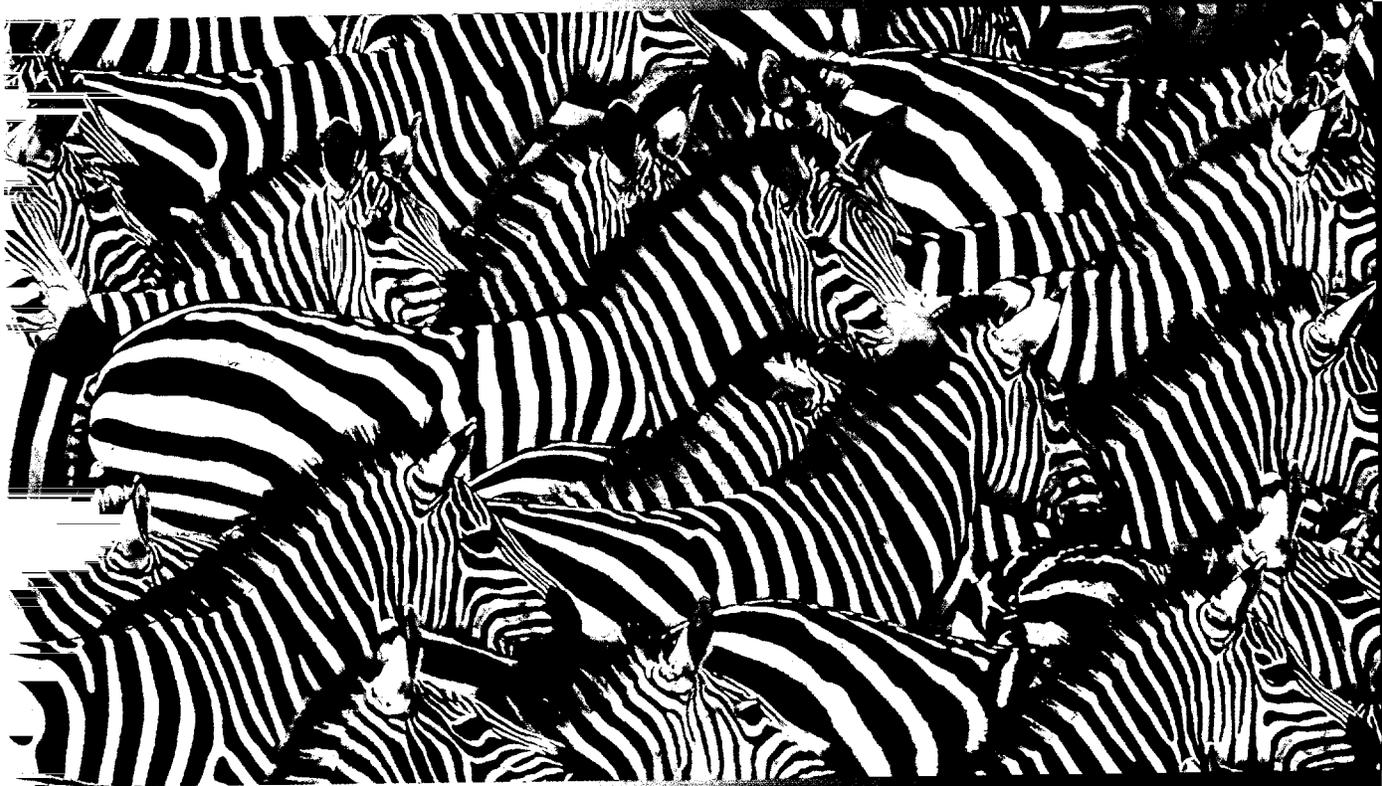
The Company's Common Stock is traded on the New York Stock Exchange under the symbol "DP."

## CORPORATE OFFICE

Diagnostic Products Corporation  
5210 Pacific Concourse Drive  
Los Angeles, CA 90045-6900  
Tel: 310.645.8200  
Fax: 310.645.9999  
E-mail: [info@dpconline.com](mailto:info@dpconline.com)  
Website: [www.dpcweb.com](http://www.dpcweb.com)

## FORWARD-LOOKING STATEMENTS

Except for historical information, this report contains forward-looking statements (identified by the words "estimate," "project," "anticipate," "plan," "except," "intend," "believe," "hope" and similar expressions) which are based upon Management's current expectations and speak only as of the date made. These forward-looking statements are subject to risks, uncertainties and factors that could cause actual results to differ materially from the results anticipated in the forward-looking statements. These risks and uncertainties include the Company's ability to successfully market new and existing products; the Company's ability to keep abreast of technological innovations and successfully incorporate them into new products; the Company's current dependence on sole suppliers for key chemical components in the IMMULITE assays; the Company's ability to address and resolve issues relating to the FDA's Application Integrity Policy on a timely basis; the Company's ability to have new tests reviewed and approved by the FDA; the risks inherent in the development and release of new products, such as delays, unforeseen costs, technical difficulties, and regulatory approvals; competitive pressures, including technological advances and patents obtained by competitors; environmental risks related to substances regulated by various federal, state, and international laws; currency risks based on the relative strength or weakness of the U.S. dollar; domestic and foreign governmental health care regulation and cost containment measures; political and economic instability in certain foreign markets; changes in accounting standards promulgated by the Financial Accounting Standards Board, the Securities and Exchange Commission, the Public Company Accounting Oversight Board, or the American Institute of Certified Public Accountants; and the effects of governmental or other actions relating to certain payments by the Company's Chinese subsidiary. These and other risks and uncertainties are discussed in greater detail from time to time in the Company's SEC filings.



[www.dpcweb.com](http://www.dpcweb.com)

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