

DATATRAK INTERNATIONAL INC

Form 10-K

March 11, 2005

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

FORM 10-K

**FOR ANNUAL AND TRANSITION REPORTS PURSUANT TO SECTIONS 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934**

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

p

For the fiscal year ended December 31, 2004

OR

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

o

For the transition period from _____ to _____

Commission file number 000-20699

DATATRAK International, Inc.

(Exact name of registrant as specified in its charter)

Ohio

34-1685364

(State or other jurisdiction of
incorporation or organization)

(I.R.S. Employer
identification no.)

6150 Parkland Boulevard, Mayfield Hts., Ohio

44124

(Address of principal executive offices)

(Zip code)

Registrant's telephone number, including area code: (440) 443-0082

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: Common Shares, without par value.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

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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.

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

Yes No

As of June 30, 2004, the aggregate market value of the 5,567,571 common shares then outstanding, which together constituted all of the voting shares of the registrant, held by non-affiliates was \$71,821,666 (based upon the closing price of \$12.90 per common share on the Nasdaq SmallCap Market on June 30, 2004). For purposes of this calculation, the registrant deems the common shares held by all of its Directors and executive officers to be the common shares held by affiliates. As of February 28, 2005, the registrant had 6,770,148 common shares, without par value, issued and outstanding.

Except as otherwise stated, the information contained in this Form 10-K is as of December 31, 2004.

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PART I

ITEM 1. BUSINESS

General

We are a provider of software and other related services, commonly referred to as an application service provider, or ASP. Our customers use our software to collect and transmit clinical trial data electronically, commonly referred to as electronic data capture, or EDC. Our customers are companies in the clinical pharmaceutical, biotechnology, contract research organization, or CRO, and medical device research industries. Our services assist these companies in accelerating the completion of clinical trials by providing improved data quality, and reducing the time required to review the results of each clinical trial.

We were founded in 1991 as a site management organization. We provided clinical research services to various clinical trial sponsors through our clinical business, which we sold in April 1999. We currently operate in one business segment as an ASP business providing EDC and other services to the clinical research industry.

We began EDC operations in 1997. During that year, we participated in a joint venture with IBM Global Services to develop and market a data collection and management system for use in clinical trials. The joint venture was terminated, and in January 1998, we purchased the software now known as DATATRAK EDC® from PadCom Clinical Research. DATATRAK EDC® was developed to provide clinical research data to sponsors of clinical trials faster and more efficiently than other forms of information-processing. Since the purchase of DATATRAK EDC®, we have devoted the majority of our efforts to developing and improving the EDC technology employed by this software, and attempting to establish the market presence necessary to compete in the evolving EDC sector of the clinical research industry.

During the second half of 2002, we took steps to streamline our cost structure primarily through staff reductions and payroll cost savings in order to allow us to lower our break-even point, and to potentially achieve profitability more quickly than previously anticipated. The benefits of these cost cutting steps along with our growth in revenue can be seen in our results of operations for 2003. During 2003, we significantly reduced our net loss to \$1,049,000 compared to a loss of \$6,391,000 in 2002.

During 2004, in conjunction with our revenue growth, our costs began to increase; however, we were able to record operating income for the first time since beginning EDC operations. Our operating income for 2004 was \$791,000.

In December 2004, we entered into an alliance agreement with SAS Institute Inc. (SAS). Pursuant to this alliance, DATATRAK and SAS will make a joint offering to customers to gather and analyze clinical trial data. During the initial two-year term of the alliance, we are obligated to make an aggregate of \$650,000 in fixed payments to SAS, for among other things, access to the SAS® Drug Development software. These fixed payments will allow us to make the SAS® Drug Development software available to our customers during the initial term of the alliance. We are also entitled to provide similar use of the SAS software to our customers during a third option year upon the payment of a \$200,000 fixed fee. We will charge fees to our customers, which utilize the SAS® Drug Development software, which will be designed to allow us to recoup some or all of the fixed fees payable to SAS.

In December 2004, we received net proceeds of approximately \$4,376,000 in connection with the consummation of a private placement of 486,313 of our common shares at a purchase price of \$9.50 per share. The terms of this financing included the issuance of three-year warrants to purchase a total of 72,948 common shares at \$14.40 per share to the investors in the private placement and the issuance of three-year warrants to purchase a total of 21,316 common shares at \$14.40 per share to a placement agent for the private placement. These 580,577 common shares

represent, assuming issuance of the 94,264 common shares underlying the warrants, 8.7% of our outstanding common shares. We expect to use the

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proceeds of the private placement to expand our worldwide marketing and sales efforts, continue investing in software development and for other general working capital purposes.

Overview of the Clinical Research Industry

Our customers are companies in the clinical pharmaceutical, biotechnology, CRO and medical device research industry. This industry is driven by regulatory requirements which mandate that new drugs and medical devices be adequately tested in clinical trials prior to marketing these drugs and devices.

Competitive and cost-containment pressures are forcing the pharmaceutical and biotechnology industries to become more efficient when developing new products. To improve returns on research and development investments, pharmaceutical and biotechnology companies are continuing to develop new products, while at the same time attempting to shorten product development timelines. These efforts have placed more drugs into the clinical development process and have increased the pressure for companies to develop products faster in order to maintain growth and continue to achieve acceptable returns on research and development expenditures. Sponsors of clinical trials have attempted to create process efficiencies, control fixed costs and expand capacity by outsourcing clinical research activities.

DATATRAK Software and Services

Under the traditional method of clinical research, clinical trial data from each patient is recorded and maintained on paper in a binder, known as a case report form. A separate case report form is maintained for each patient. Clinical research associates then visit research sites to review the clinical trial data for accuracy and integrity. During these visits, known as monitoring visits, the research associate must review each page of each case report form. These visits may last several days, and corrections to the case report forms are frequently required before the data can be delivered to the clinical trial sponsor. Several weeks, or even months, of data may be reviewed during each monitoring visit. At the completion of a monitoring visit, the completed case report form pages are physically transferred to a central location where the data is then entered into a database for statistical compilation. Using this method of data collection and quality control, the duration of the clinical trial process, from patient visit to delivery of clean data to the clinical trial sponsor, can range from six to nine months. Such delays are significant because errors or trends may not be detected until long after the interaction between the patient and clinical investigator.

DATATRAK EDC® was developed to provide clinical research data to sponsors of clinical research trials faster and more efficiently than other forms of information-processing that utilize paper. We believe that automating data entry and review procedures can save time in the drug development and medical device approval process. The DATATRAK EDC® software and its earlier versions have supported many international clinical trials involving thousands of clinical research sites and tens of thousands of patients in over 45 countries. Our product suite has been utilized in the clinical development of 14 separate drugs that have received regulatory approval from either the U.S. Food and Drug Administration (FDA) or counterpart regulatory bodies in Europe.

The DATATRAK EDC® technology platform consists of Windows compatible software and hardware designed to assist clinical trial sponsors in starting and finishing their clinical trials on a timelier and more efficient basis while also enhancing the quality of the data. In addition to providing technology, we are also a service business that offers EDC and clinical trial data management capabilities across numerous research sites. Our objective is to improve the traditional process of collecting clinical research and noninterventional health care data by providing cleaner data more quickly than what is available in a paper environment.

The DATATRAK EDC® system consists of numerous modules designed for flexible adaptation to the clinical research process. We initially provide a set of electronic data forms that can be modeled to suit the needs of each

particular clinical trial. Each form is then made available through data entry capability to each research site participating in the clinical trial via the Internet. Once clinical trial data has been collected and entered, the clinical trial sponsor, or other contracted vendor, can review the data remotely via the Internet. After the data is reviewed and cleansed of all entry errors, DATATRAK EDC®'s report

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capability can generate customized reports. Finally, the software's export feature allows completed data and reports to be transmitted directly to a clinical trial sponsor's in-house database. Under this model, research data is collected more quickly and with greater accuracy than with physical review of paper reports.

We are continually enhancing and testing the DATATRAK EDC® software suite. Recent initiatives and enhancements to the DATATRAK EDC® software include a new portal of entry for all of DATATRAK's future clinical trials called StudyTrak®, our Technology Transfer program which will allow customers to design their own EDC case report forms, and a joint venture creating an EDC certification program known as eMerge. Research and development expenses were \$1,142,000, \$850,000 and \$1,681,000 in 2004, 2003 and 2002, respectively. The decrease in our research and development expenses during 2003 was largely a result of the staff reductions and other payroll cost savings that were initiated at the end of 2002. During 2004, in conjunction with our increased revenue, we increased expenses in research and development.

Our alliance with SAS, which has been branded as DATATRAK Aware™ Powered by SAS, is designed to bring greater speed and efficiency to the conduct of clinical trials. This Alliance will directly integrate clinical trial information from DATATRAK EDC® software with SAS® Drug Development software to allow clinical trial sponsors to have immediately analyzable SAS datasets, automatically updated, for their clinical trials.

The DATATRAK EDC® software can be deployed globally via a distributed platform using laptop computers, in a centralized environment with resident hardware, or in a wireless mode, all utilizing the Internet.

Our DataUnifyer™ product will allow data from different data sources to be combined into one general repository. We began work on the prototype of the DataUnifyer™ in 2002, but delayed additional funding for this product as part of our overall cost cutting strategy implemented at the end of 2002. We anticipate significant development of the DataUnifyer™ during 2005.

Customers and Marketing

Our customers are largely comprised of clinical trial sponsors. We market our software and services through a sales and marketing staff located in the United States and Europe. The market for EDC in general and for our services specifically, has been an emerging one. Our marketing efforts have included selective participation in scientific and medical meetings to promote our services and we have occasionally used direct mail and journal advertisements to build awareness of our capabilities.

Our marketing and sales efforts have been focused upon building reference accounts with key customers and leveraging these relationships into new divisions of our current customers, and growing new customers through maintaining a high level of satisfaction in the delivery of our product suite on a worldwide basis. We are in the process of reorganizing our sales and marketing department, and expect that this reorganization, along with our SAS licensing agreement and increased acceptance of EDC, will lead to increased contract signings and backlog growth in 2005.

The EDC market has been slow to develop. The growth of the Internet has drastically altered business strategies and pricing models in this specific sector. Most EDC vendors have insignificant revenues and are classified as start-ups. Nonetheless, we believe that some type of automation in the collection and review of clinical trial data is inevitable.

It is our belief that DATATRAK EDC® can be competitive in this emerging marketplace. Our product has been tested and verified to be in compliance with FDA and other regulations. DATATRAK EDC® is delivered primarily via the Internet and supports multiple languages. Furthermore, many clinical trial sponsors have published statistics

indicating that EDC can reduce the length of time to complete a clinical trial, and can reduce the number of questions concerning the clinical trial data thereby improving the quality of the clinical trial data.

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We believe that the efficiencies represented by our relationship with SAS will further contribute to enhancing adoption rates for EDC. We plan to have our DATATRAK EDC® software automatically integrated with SAS® Drug Development software. SAS® Drug Development software is a set of tools that analyze clinical trial data. SAS data sets are the standard used in the clinical trial industry and with regulatory agencies.

The extent to which we rely on revenue from one customer varies from period to period, depending upon, among other things, our ability to generate new business, and the timing and size of clinical trials. In light of our small revenue base, we are more dependent on major customers than many of the larger participants in the EDC industry. The table below sets forth the percentage of revenue generated from customers who accounted for more than 10% of our revenue during 2004, 2003 and 2002.

| Customer | Year ended December 31, | | |
|---------------------------|-------------------------|------|------|
| | 2004 | 2003 | 2002 |
| Aventis Pharmaceuticals | 12% | 22% | 29% |
| Control Delivery Systems | * | 11% | 20% |
| Daiichi Pharmaceutical | * | * | 10% |
| Otsuka Research Institute | 45% | 20% | * |

* Less than 10% of revenue.

Contracting and Backlog

Our standard contracts with our customers provide a fixed price for each component or service to be delivered, and we recognize revenue as these components or services are delivered. Services provided by us that are in addition to those provided for in our contracts are billed on a fee-for-service basis as completed. Generally, these contracts range in duration from one to three years. The ultimate contract value is dependent upon the length of the customer's use of DATATRAK EDC® and the services we provide. As services are performed over the life of the contract, we recognize revenue per the specific terms of each contract. Costs associated with contract revenue are recognized as incurred. Our customers, with or without cause, can terminate a contract at any time. If one of our contracts is cancelled, we are entitled to payment for all work performed through the date of notice of termination and for recovery of some or all costs incurred to terminate a contract. The termination of a standard contract will not result in a material adjustment to the revenue or costs we have previously recognized.

In some instances, we offer volume discounts to customers over multiple contracts. We estimate the volume discounts to be earned over the life of the contracts to which the discount applies. As contracts progress, revenue is recorded using rates that reflect the anticipated volume discount to be achieved by the customer. The termination of a contract subject to a volume discount could result in a material adjustment to revenue previously recognized, in order to reflect the true economic value of the contract at the time of cancellation. For the year ended December 31, 2004, we deferred \$69,000 of revenue as a result of contracts subject to volume discounts. No revenue was deferred in 2003 or 2002 as a result of contracts subject to volume discounts.

Our backlog consists of anticipated revenue from authorization letters to commence services and signed contracts yet to be completed. We do not include in our backlog potential contracts or authorization letters that, regardless of whether they have passed the verbal stage, have not yet been signed. At December 31, 2004, our backlog was \$14,057,000 compared to backlog of \$14,600,000 at December 31, 2003. We expect to convert approximately \$9,200,000 of our December 31, 2004 backlog into revenue during 2005. Our contracts can be cancelled or delayed at anytime and, therefore, our backlog, at any point in time, is not an accurate predictor of future levels of revenue.

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Competition

We compete within the clinical research and the EDC markets. Both of these industries are highly competitive and fragmented. In addition, the EDC industry is currently emerging and is characterized by rapidly evolving technology. The largest competitor to the EDC market is the traditional paper-based method of collecting clinical trial data. EDC may not effectively replace paper as the preferred method of collecting and managing clinical trial data to the extent that we believe it will.

We compete in the EDC market on the strength of DATATRAK EDC®'s functionality, design architecture and data entry and review tools, which we believe equal or exceed those available in the market. As demonstrated by our alliance with SAS, we believe that we may be able to enhance our competitive strength through the formation of strategic alliances with established industry organizations.

Our major competitors include software vendors specializing in EDC, clinical trial data service companies and large pharmaceutical companies currently developing their own in-house technology. Also, many current and potential future competitors have or may have substantially greater financial and technical resources, greater name recognition and more extensive customer bases that could be leveraged, thereby gaining market share or product acceptance to our detriment. We may not be able to capture or establish the market presence necessary to effectively compete in this emerging sector of the clinical research industry.

We are aware of other EDC systems that compete or, in the future, may compete directly with DATATRAK EDC®. We also are aware of other current or developing technologies that provide some of the functionality of the DATATRAK® process. There are other companies that have developed or are in the process of developing technologies that are, or, in the future, may be, the basis for competitive products in the clinical research EDC market. Some of those technologies may have an entirely different approach or means of accomplishing the desired effects of DATATRAK EDC®. Either existing or new competitors also may develop products that are superior to or that otherwise achieve greater market acceptance than DATATRAK EDC®. In addition, we believe that certain large companies in the information technology industry may be forming alliances and attempting to capitalize on the data delivery options offered by the Internet. To the extent that our approach to EDC may gain market acceptance, larger companies in the information technology industry may develop competing technology to our detriment.

Regulatory Matters

The FDA has issued guidelines and rules on the use of computer systems in clinical trials relating to standard operating procedures, data entry, system design, security, system dependability and controls, personnel training, records inspection and certification of electronic signatures. Based on our review, we believe DATATRAK EDC® complies with these guidelines and rules. The FDA's guidelines and rules related to the use of computerized systems in clinical trials are still in the early stages of development. The DATATRAK® process may not continue to comply with these guidelines and rules as they develop, and corresponding changes to our product may be required. Any release of FDA guidance that is significantly inconsistent with the design of DATATRAK EDC® may cause us to incur substantial costs to remain in compliance with FDA guidance and regulations. We are continuing to monitor the FDA's guidance to ensure compliance.

In addition to FDA guidelines and rules, we also comply with International Conference on Harmonization (ICH) Regulations guidelines for good clinical practices. These guidelines have been developed by the ICH and have been subject to consultation by regulatory parties, in accordance with the ICH process. The regulatory bodies consist of representatives from the European Union, Japan and the U.S.

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, applies to health care providers, health plans and health care clearinghouses, or covered entities. Under HIPPA, covered entities are required to protect the confidentiality, integrity and availability of certain electronic patient information they collect, maintain, use, or transmit. Neither we, nor our customers, are covered entities under HIPPA,

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however we have taken steps, including encryption techniques, to ensure the confidentiality of all electronic patient information that is captured and transmitted through the use of DATATRAK EDC®.

Potential Liability and Insurance

Our services are supported by telecommunications equipment, software, operating protocols and proprietary applications for high-speed transmission of large quantities of data among multiple locations. In such operations, it is possible that data files may be lost, altered or distorted. DATATRAK EDC® and future enhancements or adaptations may contain undetected design faults and software bugs that, despite our testing, are discovered only after the system has been installed and used by customers. Such faults or errors could cause delays or require design modifications on our part. In addition, clinical pharmaceutical and medical device research requires the review and handling of large amounts of patient data. Potential liability may arise from a breach of contract or a loss of or unauthorized release of clinical trial data. Contracts with our customers are designed to limit our liability for damages resulting from errors in the transportation and handling of data. Nevertheless, we may still be subject to claims for data losses in the transportation and handling of data over our information technology network.

If we were forced to undertake the defense of, or were found financially responsible for, claims based upon the foregoing or related risks we could incur significant costs relating to these claims, and our financial resources could be diminished. We maintain a \$5,000,000 errors and omissions professional liability insurance policy to cover claims that may be brought against us. This coverage may not be adequate, and insurance may not continue to be available to us, in the future.

Intellectual Property

Intellectual property rights are significant to our ongoing operations and future opportunities. We have taken steps to secure patent protection for recently-developed database technology. Our software and business processes embody numerous trade secrets which we protect through various physical and technical security measures, as well as by agreement. Modules of our DATATRAK EDC® software, related manuals and other written and graphical materials are subject to copyright protection. Our DATATRAK® brand is at the heart of a family of registered trademarks and service marks that identify and distinguish our software and services in the market. We sell our services and license our software subject to contract provisions intended to provide appropriate protection to these valuable intellectual property assets.

Employees

As of February 28, 2005, we had approximately 75 full-time employees. None of our employees are represented by a union, and we consider relations with our employees to be satisfactory. We have employment agreements with all of our executive officers. Due to the early stage of development of our industry and business, the loss of the services of any of our executive officers could put us at a competitive disadvantage, since we would need to attract a qualified new executive to fill the vacancy. To address these risks, we must, among other things, continue to attract, retain and motivate qualified personnel.

Available Information

Our Internet address is www.datatrak.net. There we make available links to our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission (the Commission). Our SEC reports can be accessed through the investor relations section of our Web site. The information found on our Web site is not part of this or any other report we file with or furnish to the SEC.

Upon the receipt of a written request from any shareholder we will mail, at no charge to the shareholder, a copy of our Annual Report, including the financial statements and schedules required to be filed with the Commission pursuant to Rule 13a-1 under the Exchange Act, for our most recent fiscal year.

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We presently lease approximately 10,000 square feet of office space in Mayfield Heights, a suburb of Cleveland, Ohio. This space is used for our executive offices and U.S. operations. We also lease approximately 17,000 square feet of office space in Bonn, Germany for our European operations. We believe that our facilities are suitable and adequate for the current and anticipated conduct of our operations.

ITEM 3. LEGAL PROCEEDINGS

From time to time, DATATRAK is a party to various lawsuits arising in the ordinary course of business. We do not believe that the outcome of any current such litigation will have a material adverse effect on its results of operations or financial condition.

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

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

PART II**ITEM 5. MARKET FOR REGISTRANT'S COMMON SHARES AND RELATED SHAREHOLDER MATTERS**

Our common shares are traded on The Nasdaq SmallCap Market under the symbol DATA.

Our common shares were initially offered to the public on June 11, 1996 at a price of \$13.50 per share and commenced trading on Nasdaq on that date. The following table sets forth, for the years ended December 31, 2004 and 2003, the high and low sale prices per common share, as reported by Nasdaq. These prices do not include retail markups, markdowns or commissions.

| | 2004 | High | Low |
|----------------|------|----------|---------|
| First Quarter | | \$ 10.16 | \$ 6.09 |
| Second Quarter | | \$ 13.22 | \$ 9.08 |
| Third Quarter | | \$ 13.22 | \$ 9.20 |
| Fourth Quarter | | \$ 12.30 | \$ 9.80 |
| | 2003 | High | Low |
| First Quarter | | \$ 1.76 | \$ 0.75 |
| Second Quarter | | \$ 4.00 | \$ 1.16 |
| Third Quarter | | \$ 6.20 | \$ 3.83 |
| Fourth Quarter | | \$ 7.50 | \$ 3.97 |

On February 28, 2005, the last sale price of our common shares as reported by Nasdaq was \$16.00 per share. As of February 28, 2005, we had 103 shareholders of record.

We have never declared or paid cash dividends on our common shares. Any determination to pay cash dividends in the future will be at the discretion of our Board of Directors after taking into account various factors, including our financial condition, results of operations, current and anticipated cash needs and plans for expansion.

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| | Year Ended December 31, | | | | |
|---|---------------------------------------|------------|------------|------------|------------|
| | 2004 | 2003 | 2002 | 2001 | 2000 |
| | (In thousands, except per share data) | | | | |
| Statement of Operations Data: | | | | | |
| Revenue | \$ 11,305 | \$ 7,052 | \$ 4,721 | \$ 2,246 | \$ 1,994 |
| Direct costs | 2,634 | 1,622 | 1,804 | 1,780 | 1,597 |
| Gross profit | 8,671 | 5,430 | 2,917 | 466 | 397 |
| Selling, general and administrative expenses | 7,229 | 5,551 | 7,893 | 7,210 | 5,726 |
| Special items | | | 364 | | |
| Depreciation and amortization | 651 | 937 | 1,122 | 949 | 867 |
| Income (loss) from operations | 791 | (1,058) | (6,462) | (7,693) | (6,196) |
| Other income, net | 35 | 14 | 71 | 339 | 912 |
| Income (loss) before income taxes | 826 | (1,044) | (6,391) | (7,354) | (5,284) |
| Income tax expense | 9 | 4 | | | |
| Net income (loss) | \$ 817 | \$ (1,048) | \$ (6,391) | \$ (7,354) | \$ (5,284) |
| Net income (loss) per share: basic | \$ 0.13 | \$ (0.19) | \$ (1.22) | \$ (2.23) | \$ (1.61) |
| Shares used in the computation of basic net income (loss) per share | 6,099 | 5,565 | 5,237 | 3,291 | 3,290 |
| Net income (loss) per share: diluted | \$ 0.12 | \$ (0.19) | \$ (1.22) | \$ (2.23) | \$ (1.61) |
| Shares used in the computation of diluted net income (loss) per share | 6,825 | 5,565 | 5,237 | 3,291 | 3,290 |

| | December 31, | | | | |
|---|---------------------------------------|----------|----------|----------|-----------|
| | 2004 | 2003 | 2002 | 2001 | 2000 |
| | (In thousands, except per share data) | | | | |
| Balance Sheet Data: | | | | | |
| Cash, cash equivalents and short-term investments | \$ 7,919 | \$ 4,261 | \$ 2,244 | \$ 4,912 | \$ 12,040 |
| Working capital | 8,575 | 3,468 | 1,380 | 4,129 | 11,645 |
| Total assets | 11,941 | 6,377 | 5,306 | 7,634 | 14,486 |
| Long-term liabilities | | | 24 | 162 | |
| Accumulated deficit | (30,964) | (31,781) | (30,732) | (24,341) | (16,987) |
| Total shareholders' equity | 10,117 | 4,601 | 3,231 | 5,755 | 13,104 |
| Book value per common share | \$ 1.53 | \$ 0.77 | \$ 0.61 | \$ 1.75 | \$ 3.98 |
| Cash dividends declared | | | | | |

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

General

We are an ASP that provides EDC and other services to companies in the clinical pharmaceutical, biotechnology, CRO and medical device research industries. We assist our customers in accelerating the completion of clinical trials by streamlining the collection of data relating to clinical trials, and improving the overall quality of the clinical trial data collected.

The discussion that follows highlights our business conditions and certain financial information. This discussion and analysis should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

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Approximately 66% of our assets, or \$7,919,000, is held in cash, cash equivalents and short-term investments. During 2004, and for the first time since commencing EDC operations in 1997, we recorded operating income. We are continuing to develop and commercialize our business, and anticipate that our operating results will fluctuate significantly from period to period.

We use a technology platform that consists of Windows compatible software and internet hardware known as DATATRAK EDC® to provide EDC and other services to clinical trial sponsors and CROs. Our future success is dependent on market acceptance of EDC in general, as an alternative to the traditional paper method of collecting clinical trial data, and acceptance of DATATRAK EDC® specifically. We may be unsuccessful in achieving commercial acceptance of the DATATRAK® process.

At December 31, 2004, our backlog was \$14,057,000 compared to backlog of \$14,600,000 at December 31, 2003. Our December 31, 2004 backlog consisted of 58 contracts with an average remaining value of \$242,000. At December 31, 2003, our backlog consisted of 45 contracts with an average remaining value of \$324,000. Our contracts in backlog at December 31, 2003 generated \$9,402,000 of revenue during 2004. If we have no delays or cancellations to the contracts in backlog at December 31, 2004, we expect to convert approximately \$9,200,000 of our December 31, 2004 backlog into revenue during 2005. Our contracts can be cancelled or delayed at anytime and, therefore, our backlog, at any point in time, is not an accurate predictor of future levels of revenue.

Critical Accounting Policies

In response to the SEC's Release No. 33-8040, *Cautionary Advice Regarding Disclosure About Critical Accounting Policies*, we have identified the most critical accounting principles upon which our financial status depends. Critical principles were determined by considering accounting policies that involve the most complex or subjective decisions or assessments. The most critical accounting policies were identified to be those related to revenue recognition, software development costs and stock based compensation.

Revenue Recognition

Our standard contracts provide a fixed price for each component or service to be delivered, and revenue is recognized as these components or services are delivered. Services we provide that are in addition to those provided for in our contracts are billed on a fee for service basis as services are completed. As services are performed over the life of the contract, we recognize revenue per the specific terms of each contract. Costs associated with contract revenue are recognized as incurred. Pass-through costs that are paid directly by our customers, and for which we do not bear the risk of economic loss, are excluded from revenue. The termination of a standard contract will not result in a material adjustment to the revenue or costs previously recognized.

In some instances, we offer volume discounts to customers over multiple contracts. We estimate the volume discounts to be earned over the life the contracts to which the discount applies. As contracts progress, revenue is recorded using rates that reflect the anticipated volume discount to be achieved by the customer. The termination of a contract subject to a volume discount could result in a material adjustment to revenue previously recognized, in order to reflect the true economic value of the contract at the time of cancellation. For the year ended December 31, 2004, we deferred \$69,000 of revenue as a result of contracts subject to volume discounts. No revenue was deferred in 2003 or 2002 as a result of volume discounts.

Software Development Costs

Development costs incurred in the research and development of new software products and enhancements to existing software products are expensed as incurred until technological feasibility has been established. After

technological feasibility is established, any additional costs are capitalized in accordance with Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standards (SFAS) No. 86, Accounting for the Costs of Computer Software to be Sold, Leased, or

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Otherwise Marketed. Such costs are amortized over the lesser of three years or the economic life of the related product. We perform an annual review of the recoverability of such capitalized software costs. At the time a determination is made that capitalized amounts are not recoverable based on the estimated cash flows to be generated from the applicable software, any remaining capitalized amounts are expensed.

Stock Based Compensation

We account for stock based compensation in accordance with Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees for stock options granted to employees and directors. We follow the alternative fair value accounting provided for under SFAS No. 123, Accounting for Stock-Based Compensation for stock options granted to non-employees. SFAS No. 123 requires use of option valuation models that were not developed for use in valuing employee stock options. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. SFAS No. 148 requires disclosure of compensation expense under both APB No. 25 and SFAS No. 123. SFAS No. 123 requires that stock compensation be determined as if we had accounted for our stock options granted subsequent to December 31, 1994 under the fair value method of SFAS 123. The following assumptions were used to estimate the fair value for these options using the Black-Scholes option pricing model.

| | Year ended December 31 | | |
|---|-------------------------------|-------------|-------------|
| | 2004 | 2003 | 2002 |
| Weighted average risk free interest rate | 4.1% | 4.3% | 4.3% |
| Weighted average volatility of the expected market price of the common shares | 1.01 | 1.15 | 1.36 |
| Dividend yield | 0.0% | 0.0% | 0.0% |
| Weighted-average expected life of the option | 8 years | 7 years | 7 years |
| Weighted-average fair value per share of options granted | \$9.91 | \$3.86 | \$2.53 |

For purposes of pro forma disclosures, the estimated value of the options is amortized to expense over the options vesting period. The pro forma results are not necessarily indicative of what would have occurred had we adopted SFAS No. 123.

The following table sets forth stock based compensation and pro forma information for each period presented.

| | Year ended December 31, | | |
|---|--------------------------------|----------------|----------------|
| | 2004 | 2003 | 2002 |
| Net income (loss) recorded | \$ 817,000 | \$ (1,049,000) | \$ (6,391,000) |
| Plus: stock compensation expense recognized | 40,000 | 68,000 | 15,000 |
| Less: stock compensation expense that would have been recognized under SFAS No. 123 | 736,000 | 634,000 | 392,000 |
| Pro forma net income (loss) | \$ 121,000 | \$ (1,615,000) | \$ (6,768,000) |
| Pro forma basic income (loss) per share | \$ 0.02 | \$ (0.30) | \$ (1.36) |
| Pro forma diluted income (loss) per share | \$ 0.02 | \$ (0.30) | \$ (1.36) |

Recently Issued Accounting Standards

On December 16, 2004, the FASB issued SFAS No. 123(revised 2004), Share-Based Payment , which is a revision of SFAS No.123. SFAS No. 123(R) supercedes APB No. 25, and amends SFAS No. 95, Statement of Cash Flows. Generally the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share based payments to employees,

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including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative.

We must adopt SFAS 123(R) no later than July 1, 2005. Early adoption will be permitted in periods in which financial statements have not been issued. We will adopt SFAS No. 123(R) on July 1, 2005. We will adopt SFAS No. 123 using the modified prospective method in which compensation cost is recognized beginning with the effective date based on the requirements of SFAS No. 123(R) for all share based payments granted after the effective date, and based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123(R) that remain unvested at the effective date.

As permitted by SFAS No. 123, we currently account for share based payments to employees using APB No. 25's intrinsic value method, and as such, generally recognize no compensation cost for employee stock options. Accordingly, the adoption of SFAS 123(R)'s fair value method will have a significant impact on our results of operations, although it will have no impact on our overall financial position. The adoption of SFAS 123(R) will increase our operating expenses by approximately \$1,400,000 beginning in July 2005 through December 2008 for options that remain unvested as of July 1, 2005. The full impact of adoption of SFAS No. 123(R) cannot be predicted at this time because it will depend on levels of share based payments in the future. However, had we adopted SFAS No. 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS No. 123 as described in the disclosure of pro forma net income and earnings per share in Management's Discussion and Analysis of Financial Condition and Results of Operations - Critical Accounting Policies in the Company's Annual Report on Form 10-K.

Results of Operations

Our revenue growth has been hampered by the slow growth of the EDC market. However, our revenue was able to grow from \$4,721,000 in 2002 to \$7,052,000 in 2003 and \$11,305,000 in 2004. In conjunction with the growth in revenue, our operating expenses increased to \$10,514,000 in 2004. Personnel costs represented approximately 55.0%, or 5,813,000 of our operating costs during 2004. We had approximately 80 employees at December 31, 2004. Our continued growth in revenue allowed us to record operating income, for the first time since commencing EDC operations, in the amount of \$791,000.

During 2002 we recorded a net operating loss of \$6,462,000. During 2002 our operating expenses were \$11,183,000, including special items of \$364,000. Our personnel costs represented approximately 54.0% of our operating expenses, or \$5,993,000, in 2002. We had approximately 60 employees at December 31, 2002. During the second half of 2002, we took steps to reduce our annual operating costs, primarily through reductions in personnel costs. These cost cutting measures enabled us to reduce our personnel costs to \$4,299,000 and our total operating expenses to \$8,110,000 during 2003. At December 31, 2003 we had approximately 65 employees. Our growth in revenue together with the decrease in our operating expenses allowed us to reduce our net operating loss to \$1,058,000 in 2003.

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The following table shows, for the periods indicated, selected items from our Consolidated Statements of Operations, expressed as a percentage of revenue.

| | Year Ended December 31, | | |
|--|-------------------------|--------|---------|
| | 2004 | 2003 | 2002 |
| Revenue | 100.0% | 100.0% | 100.0% |
| Direct costs | 23.3 | 23.0 | 38.2 |
| Gross profit | 76.7 | 77.0 | 61.8 |
| Selling, general and administrative expenses | 63.9 | 78.7 | 167.2 |
| Special items | | | 7.7 |
| Depreciation and amortization | 5.7 | 13.3 | 23.8 |
| Income (loss) from operations | 7.1 | (15.0) | (136.9) |
| Other income, net | 0.3 | 0.2 | 1.5 |
| Net income (loss) before income taxes | 7.4 | (14.8) | (135.4) |
| Income tax expense | 0.1 | 0.1 | |
| Net income (loss) | 7.3 | (14.9) | (135.4) |

Year ended December 31, 2004 compared with year ended December 31, 2003

Revenue for the year ended December 31, 2004 increased by 60.3% to \$11,305,000, compared to \$7,052,000 for the year ended December 31, 2003. Included in revenue for the year ended December 31, 2003, is a one-time fee of \$150,000. The \$150,000 fee relates to consulting work performed for a current customer that was outside of a traditional EDC contract. During the year ended December 31, 2004, we recorded revenue related to 69 contracts compared to 56 contracts during 2003. For the year ended December 31, 2004, \$9,402,000 of revenue was the result of contracts that were in backlog at December 31, 2003 and \$1,903,000 was the result of new business. For the year ended December 31, 2003, \$4,700,000 of revenue was generated from contracts that were in backlog at December 31, 2002 and \$2,352,000 of revenue was the result of new business.

Direct costs of revenue, mainly personnel costs, were \$2,634,000 and \$1,622,000 during the years ended December 31, 2004 and 2003, respectively. Additional staff and other payroll cost increases accounted for \$708,000 of the \$1,012,000 increase in 2004. Third party license fees, as a result of our license agreements with Microsoft and SAS increased by \$163,000 during 2004. Other direct costs, which are primarily travel and other costs billed directly to our customers, increased by \$141,000 during the year ended December 31, 2004. The increase in staff was necessitated by the growth in revenue and the increase in the number of contracts we have been managing over the past year. Our gross margin decreased to 76.7% for the year ended December 31, 2004 compared to 77.0% for the year ended December 31, 2003. The \$150,000 one-time revenue item caused a 0.5% increase in gross margin 2003. We anticipate that our gross margin will be approximately 75% for the year ending December 31, 2005.

Selling, general and administrative (SG&A) expenses include all administrative personnel costs, business and software development costs, and all other expenses not directly chargeable to a specific contract. These expenses increased by 31.1% to \$7,229,000 from \$5,551,000 for the years ended December 31, 2004 and 2003, respectively. Additional staff, other payroll cost increases and our new sales incentive and corporate performance bonus plans accounted for \$806,000 of the \$1,678,000 increase. Expenses related to equipment maintenance and software licensing increased \$168,000 compared to the prior year. The increase in these expenses is related to the growth of our information technology infrastructure, and is necessary to ensure that our IT infrastructure is properly maintained. Consulting costs, primarily associated with non-capitalized software development and testing, increased by \$321,000 during 2004. Cost increases in other areas, primarily due to the increased marketing of DATATRAK EDC®, and development of the Company's corporate infrastructure, resulted in additional expenses of \$383,000 during the year

ended December 31, 2004. We anticipate approximately a 35% to 40% SG&A increase in 2005 compared to 2004 as a result of increased personnel, the requirements of SFAS No. 123(R) and growth of the business.

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Depreciation and amortization expense fell to \$651,000 during the year ended December 31, 2004, from \$937,000 during the year ended December 31, 2003. The decrease was the result of aging assets, whose replacement was deferred to future periods, not being replaced as indicated by the low level of capital expenditures during 2003 of \$184,000. During 2004, we increased capital expenditure spending to a total of \$1,054,000 and expect our depreciation and amortization expense to grow accordingly in 2005.

Other income for the year ended December 31, 2004 totaled \$35,000, compared to \$14,000 for the year ended December 31, 2003. Other income includes interest income, which increased \$17,000 for the year ended December 31, 2004 compared to December 31, 2003 primarily due to increasing interest rates, during the year.

During 2004, we provided for U.S. federal alternative minimum tax of \$9,000. Due to our net loss carryforwards, we had no other federal, state or local income tax expense in 2004. At December 31, 2004 we had a net operating loss carryforward of \$20,071,000 for United States income tax purposes. An equity transaction completed on January 7, 2002 has limited our net operating loss carryforwards, incurred prior to that date, to a maximum amount of \$967,000 per year, under Section 382 of the Internal Revenue Code. All of our United States net operating loss carryforwards will begin expiring in the year 2018 and will be fully expired in the year 2022. The Company also has a net operating loss carryforward of approximately 10,332,000 Euro for German income tax purposes with no expiration date. Due to the uncertainty of the recoverability of our deferred tax assets, we have fully provided for our deferred tax assets through a valuation allowance.

Year ended December 31, 2003 compared with year ended December 31, 2002

Revenue for the year ended December 31, 2003 increased by 49.4% to \$7,052,000, compared to \$4,721,000 for the year ended December 31, 2002. Included in revenue for the year ended December 31, 2003, is a one-time fee of \$150,000. The \$150,000 fee relates to consulting work performed for a current customer that was outside of a traditional EDC contract. The remainder of the increase was due largely to greater acceptance of the DATATRAK EDC® software by clinical trial sponsors, resulting in an increase in the number of clinical trials using the DATATRAK EDC® software. During 2003, we recorded revenue related to 56 contracts compared to 41 contracts during 2002.

Direct costs of revenue, mainly personnel costs, were \$1,622,000 and \$1,804,000 during the years ended December 31, 2003 and 2002, respectively. Our gross profit was \$5,430,000 and \$2,917,000 during 2003 and 2002, respectively. Personnel costs decreased by \$132,000 during 2003 due to the cost cutting measures implemented at the end of 2002. Also during 2003 our internet service provider costs decreased by \$107,000 due to decreasing rates. These decreases were offset by a \$57,000 increase in other direct costs. These other direct costs are mainly travel expenses and other costs, which are billed to our customers. The \$182,000 decrease in direct costs combined with our increased revenue resulted in a gross margin of 77.0% in 2003 compared to 61.8% in 2002.

SG&A expenses include all administrative personnel costs, business and software development costs, and all other expenses not directly chargeable to a specific contract. These expenses decreased by 29.7% to \$5,551,000 from \$7,893,000 for the years ended December 31, 2003 and 2002, respectively. Staff reductions and other payroll cost savings caused personnel costs to decrease by \$1,562,000 during the year ended December 31, 2003. Cost reductions in other areas resulted in additional savings of \$780,000 during the year ended December 31, 2003. The decrease in SG&A expenses is consistent with what we anticipated when staff reductions and other cost-cutting measures were implemented at the end of 2002.

Depreciation and amortization expense fell to \$937,000 during the year ended December 31, 2003, from \$1,122,000 during the year ended December 31, 2002. The decrease was the result of aging assets, whose replacement was deferred to future periods, not being replaced as indicated by the low level of capital expenditures during 2003.

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Other income for the year ended December 31, 2003 totaled \$14,000, compared to \$72,000 for the year ended December 31, 2002. Other income includes interest income, which decreased \$64,000 for the year ended December 31, 2003 compared to December 31, 2002 primarily due to our use of cash to fund operating losses and other working capital needs.

During 2003, we had federal alternative minimum tax of \$4,000 due to income earned by our U.S. based operations. Due to our consolidated net loss and our net operating loss carryforwards, we had no other federal, state or local income tax expense in 2003.

Outlook

Primarily due to our growth in revenue, we reported operating income for the first time in our EDC history during 2004. Backlog at December 31, 2004 of \$14,057,000 was less than backlog reported at December 31, 2003 of \$14,600,000 because new contract signings have been less than anticipated during the past year. We are in the process of reorganizing our sales and marketing department and expect that this reorganization, along with our SAS alliance and increased acceptance of EDC, will lead to increased contract signings and backlog growth in 2005.

We believe that shareholders can anticipate revenue to grow by approximately 50% for the year ending December 31, 2005 compared to 2004. We expect our revenue to grow gradually on a quarter to quarter basis. This growth in revenue assumes that there will be no contract delays or cancellations to current projects and we achieve our internal projections for additional new business. We expect that approximately \$9,200,000 of our 2005 revenue will come from contracts that were in backlog at December 31, 2004, and the remainder will be from contracts signed and anticipated to be signed during 2005. We expect our gross margin to be at the 75% level for 2005. SG&A Expenses are expected to increase by 35% to 40% in 2005 as compared to 2004. Our effective tax rate for 2005 is expected to be approximately 3% due to the use of our net operating loss carry-forwards.

Liquidity and Capital Resources

Our principal sources of cash have been cash flow from operations and proceeds from the sale of equity securities. Our investing activities primarily reflect capital expenditures and purchases and maturities of short-term investments. In December 2004 we received approximately \$4,376,000 in net proceeds from the completion of a private placement of our common shares.

Contracts with our customers usually require a portion of the contract amount to be paid at the time the contract is initiated. Additional payments are generally received monthly as work on the contract progresses. We record all amounts received as a liability (deferred revenue) until work has been completed and revenue is recognized. Cash receipts do not necessarily correspond to costs incurred or revenue recognized. We typically receive a low volume of large-dollar receipts. Our accounts receivable will fluctuate due to the timing and size of cash receipts. Our contracting and collection practices are designed to maintain an average collection period for accounts receivable of one to three months. Any increase in our normal collection period for accounts receivable could negatively impact our cash flow from operations and our working capital. At December 31, 2004, our average collection period for accounts receivable was 45 days compared to 43 days at December 31, 2003. Accounts receivable (net of allowance for doubtful accounts) was \$1,990,000 at December 31, 2004 and \$788,000 at December 31, 2003. Our increased revenue has caused the growth in accounts receivable. Deferred revenue was \$585,000 at December 31, 2004 compared to \$897,000 at December 31, 2003.

Cash and cash equivalents increased \$505,000 during the year ended December 31, 2004. This was the result of \$4,741,000 provided by financing activities, offset by \$63,000 and \$4,156,000 used by operating and investing activities, respectively. Foreign currency fluctuations caused a \$17,000 decrease in cash and cash equivalents. Cash

used in operating activities was the result of the Company's net income of \$817,000, plus non cash operating items of \$682,000. This \$1,499,000 increase was offset by the \$1,212,000 increase in accounts receivable, caused by the Company's growth in revenue during 2004, and the \$312,000 decrease in deferred revenue. Changes in other current assets and liabilities caused cash from

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operating activities to increase by \$38,000. Investing activities included net cash uses of \$3,126,000 from purchases and maturities of short-term investments, \$1,054,000 used to purchase property and equipment and a \$24,000 decrease in our restricted cash balance. Financing activities included \$4,764,000 in cash received from our private placement of common shares and other equity transactions, and \$24,000 used to repay a capital lease obligation.

At December 31, 2004, we had working capital of \$8,575,000, and our cash, cash equivalents and short-term investments totaled \$7,919,000. Our working capital has increased by \$5,107,000 since December 31, 2003. The increase was the result of the \$3,658,000 increase in our cash, cash equivalents and short-term investments, due mainly to our private placement of common shares, a \$1,202,000 increase in accounts receivable (net of allowance for doubtful accounts) and a \$312,000 decrease in deferred revenue. Changes in other current assets and liabilities caused working capital to decrease by \$65,000.

We are party to a lease agreement that requires us to maintain a restricted cash balance. Our restricted cash balance was \$81,000 at December 31, 2004.

We intend to continue to fund the enhancement and testing of the DATATRAK EDC® software, as well as continue to invest in the development of the DATATRAK® process. Our operations and the EDC market are still in a developmental stage. We have experienced revenue growth; and anticipate positive cash flow from operations during 2005 as we continue to build our customer base, increase our backlog and convert our current backlog into revenue. We anticipate capital and related expenditures of approximately \$1,300,000 for the twelve months ending December 31, 2005, for the continued commercialization and enhancement of DATATRAK EDC®. Of the \$1,300,000 total, \$1,000,000 is required to maintain and upgrade current systems. The remaining \$300,000 is in conjunction with the anticipated growth of our business, and is to some extent discretionary. Additionally, we anticipate spending approximately \$400,000 for maintenance of our information technology infrastructure during 2005.

Our research and development expenditures have historically been for the continued enhancement of and modifications to our DATATRAK EDC® software. During 2005, we anticipate spending approximately \$1,800,000 for research and development. Research and development expenditures will increase approximately \$700,000 compared to 2004. Our 2005 research and development expenditures will be for the continued enhancement and modifications to our DATATRAK EDC® software, the integration DATATRAK EDC® with SAS® Drug Development software and the development of our DataUnifyer product.

We expect to fund our working capital requirements, from existing cash and cash equivalents, maturities of short-term investments and cash flow from operations. We believe that, with the continued anticipated growth in revenue, our cash and cash equivalents, maturities of short-term investments and cash flow from operations will be sufficient to meet our working capital and capital expenditure requirements for the foreseeable future. However, we may need to raise additional funds to offset delays or cancellations of contracts, support expansion, respond to competitive pressures, acquire complementary businesses or technology or take advantage of unanticipated opportunities. We may raise additional funds by selling debt or equity securities, by entering into strategic relationships or through other arrangements. Additional capital may not be available on acceptable terms, if at all. To the extent that additional equity capital is raised, it could have a dilutive effect on our existing shareholders.

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The table below shows our contractual cash obligations, expressed in thousands, at December 31, 2004.

| Contractual Obligations | Total | Payments Due by Period | | | |
|------------------------------------|----------|------------------------|--------------|--------------|------------------|
| | | Less than 1 year | 1 3 years | 3 5 years | After 5 years |
| Operating leases | \$ 3,714 | \$ 592 | \$ 1,147 | \$ 1,004 | \$ 971 |
| Purchase obligations | 400 | 250 | 150 | | |
| Total contractual cash obligations | \$ 4,114 | \$ 842 | \$ 1,297 | \$ 1,004 | \$ 971 |

Our purchase obligations consist of the payments to SAS for among other things, access to the SAS® Drug Development software. The first payment of \$250,000 was made in December 2004. The payments to SAS totaling \$650,000, the last of which will be made by the end of January, 2006, will be expensed on a straight line basis over the two year life of the alliance agreement. Any incremental data item fees associated with the alliance will be expensed as incurred.

Inflation

To date, we believe that the effects of inflation have not had a material adverse effect on our results of operations or financial condition.

Interest Rate Risk

We have fixed income investments consisting of cash equivalents and short-term investments, which may be affected by changes in market interest rates. We do not use derivative financial instruments in our investment portfolio. We place our cash equivalents and short-term investments with high-quality financial institutions, limit the amount of credit exposure to any one institution and have established investment guidelines relative to diversification and maturities designed to maintain safety and liquidity. Investments are reported at amortized cost, which approximates fair value.

Foreign Currency Risk

Our foreign results of operations are subject to the impact of foreign currency fluctuations through both foreign currency transaction and foreign currency translation adjustments. We manage our risk to foreign currency transaction adjustments by maintaining foreign currency bank accounts in currencies in which we regularly transact business. We do not currently hedge against the risk of exchange rate fluctuations.

Our financial position and results of operations are impacted by translation adjustments caused by the conversion of foreign currency accounts and operating results into U.S. dollars for financial reporting purposes. During 2004 the average exchange rate between the Euro and the U.S. dollar increased by approximately 10%. The conversion of our foreign operations into U.S. dollars upon consolidation resulted in net income that was approximately \$317,000 lower than would have been recorded had the exchange rate between the Euro and the U.S. dollar remained consistent with 2003 rates.

INFORMATION ABOUT FORWARD-LOOKING STATEMENTS

Certain statements made in this Annual Report on Form 10-K contain forward-looking statements within the meaning of Section 21E of the Securities Exchange Act of 1934 (Exchange Act). All statements that address operating performance, events or developments that we anticipate will occur in the future, including statements related to future revenue, profits, expenses, income and earnings per share or statements expressing general optimism about future results, are forward-looking statements. In addition,

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words such as expects, anticipates, intends, plans, believes, estimates, variations of such words, and similar expressions are intended to identify forward-looking statements. Forward-looking statements are subject to the safe harbors created in the Exchange Act.

Forward-looking statements are subject to numerous assumptions and risks and uncertainties that may cause our actual results or performance to be materially different from any future results or performance expressed or implied by the forward-looking statements. We have identified the following important factors, which could cause our actual operational or financial results to differ materially from any projections, estimates, forecasts or other forward-looking statements made by or on our behalf. Under no circumstances should the factors listed below be construed as an exhaustive list of all factors that could cause actual results to differ materially from those expressed in forward-looking statements. We undertake no obligation to review or confirm analysts' expectations or estimates or to release publicly any revisions to forward-looking statements contained herein to take into account events or circumstances that occur after the date of this Annual Report on Form 10-K. In addition, we do not undertake any responsibility to update publicly the occurrence of unanticipated events, which may cause actual results to differ from those expressed or implied by the forward-looking statements contained herein.

We have a limited operating history and we have not until recently had profitable operations.

We began providing EDC services in 1997 and have a limited operating history upon which you may evaluate our performance. Although we were profitable in 2004, we had previously recognized operating losses in each year since 1997. Our cumulative operating loss since 1997 from EDC operations totaled \$38,584,000 at December 31, 2004. We anticipate that we will be profitable in 2005. However any number of factors, including, but not limited to, termination or delays in contracts, inability to grow and convert backlog into revenue or being able to quickly reduce costs if required, could cause us to record losses in 2005 and in future periods.

If we do not continue to enhance our software, we may not be able to meet the evolving needs of our customers.

Although our proprietary DATATRAK EDC® software has been used in clinical trials, continued enhancement is necessary to provide additional functions and services to meet the ever-changing needs and expectations of our customers. To date we have had limited EDC revenue from which to support the costs of this continued software enhancement. Our potential future revenue may not be sufficient to absorb corporate overhead and other fixed operating costs that will be necessary for the success of the DATATRAK® process.

Our quarterly results fluctuate significantly.

We are subject to significant fluctuations in quarterly results caused by many factors, including

our success in obtaining new contracts,

the size and duration of the clinical trials in which we participate, and

the timing of clinical trial sponsor decisions to conduct new clinical trials or cancel or delay ongoing trials. Our expense levels are based in part on our expectations as to future revenue and to a certain extent are fixed. We cannot assure you as to our revenues in any given period, and we may be unable to adjust expenses in a timely manner to compensate for any unexpected revenue shortfall. As a result of our relatively small revenue base, any significant shortfall in revenue recognized during a particular period could have an immediate adverse effect on our income from operations and financial condition. Volatility in our quarterly results may adversely affect the market price of our common shares.

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Our business strategies are unproven and we are in an early stage of development.

Our efforts to establish a standardized EDC process for collection and management of clinical research data represent a significant departure from the traditional clinical research practices of clinical trial sponsors. The long-term viability of our business remains unproven. Our strategy may not gain acceptance among sponsors of clinical research, research sites or investigators. Our prospects must be considered in light of the risks, expenses and difficulties frequently encountered by companies in their early stages of development, particularly companies in new and rapidly evolving markets.

We may lose revenue if we experience delays in clinical trials or if we lose contracts.

Although our contracts provide that we are entitled to receive revenue earned through the date of termination, our customers generally are free to delay or terminate a clinical trial or our contract related to the trial at any time. The length of a typical clinical trial contract varies from several months to several years. Clinical trial sponsors may delay or terminate clinical trials for several reasons, including

unexpected results or adverse patient reactions to a potential product,

inadequate patient enrollment or investigator recruitment,

manufacturing problems resulting in shortages of a potential product, or

decisions by the sponsor to de-emphasize or terminate a particular trial or drug.

We may lose revenues if a clinical trial sponsor decides to delay or terminate a trial in which we participate.

We may lose future revenue if our major customers decrease their research and development expenditures, or if we lose any of our major customers.

Our primary customers are companies in the pharmaceutical industry. Our business is substantially dependent on the research and development expenditures of companies in this industry. The extent to which we rely on revenue from one customer varies from period to period, depending upon, among other things, our ability to generate new business, the timing and size of clinical trials. In light of our small revenue base, we are more dependent on major customers than many of the larger participants in the EDC industry. During 2004, two customers accounted for 57% of our total revenue for the year. Our operations could be materially and adversely affected by, among other things,

any economic downturn or consolidations in the pharmaceutical or biotechnology industries,

any decrease in these industries' research and development expenditures, or

a change in the regulatory environment in which companies in these industries operate.

Changes in government regulations relating to the health care industry could have a material adverse effect on the demand for our services.

Demand for our services is largely a function of the regulatory requirements associated with the approval of a New Drug Application by the FDA. These requirements are more stringent and thus more burdensome than those imposed by many other developed countries. In recent years, efforts have been made to streamline the drug approval process and coordinate U.S. standards with those of other developed countries. Changes in the level of regulation, including a relaxation in regulatory requirements or the introduction of simplified drug approval procedures could reduce the demand for our services. Several

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competing proposals to reform the system of health care delivery in the United States have been considered by Congress from time to time. To date, none of these proposals have been adopted.

The FDA's guidelines and rules related to the use of computerized systems in clinical trials are still in the early stages of development. The DATATRAK® process may not continue to comply with these guidelines and rules as they develop, and corresponding changes to our product may be required. Any release of FDA guidance that is significantly inconsistent with the design of DATATRAK EDC® may cause us to incur substantial costs to remain in compliance with FDA guidance and regulations.

We may not be able to capture or establish the market presence necessary to compete in the EDC market.

The EDC market, which is still developing, and must compete with the traditional paper method of collecting clinical trial data, is highly fragmented. The major competitors, in the EDC market, include

EDC software vendors,

clinical trial data service companies that use paper for data collection, and

in-house development efforts within large pharmaceutical companies.

Our current and potential future competitors have or may have substantially greater resources, greater name recognition and more extensive customer bases that could be leveraged, thereby gaining market share or product acceptance to our detriment. We may not be able to capture or establish the market presence necessary to effectively compete in this emerging sector of the clinical research industry.

We may be subject to liability for potential breaches of contracts or losses relating to the unauthorized release of clinical trial data.

Our services are supported by telecommunications equipment, software, operating protocols and proprietary applications for high-speed transmission of large quantities of data among multiple locations. In addition, clinical pharmaceutical and medical device research requires the review and handling of large amounts of patient data. Potential liability may arise from a breach of contract or a loss of or unauthorized release of clinical trial data. If we were forced to undertake the defense of, or were found financially responsible for, claims based upon these types of losses, our financial resources could be diminished. We maintain a \$5,000,000 errors and omissions professional liability insurance policy to cover claims that may be brought against us. This coverage may not be adequate, and insurance may not continue to be available to us, in the future.

We will incur increased costs as a result of recently enacted and proposed changes in laws and regulations relating to corporate governance matters and public disclosure.

Recently enacted and proposed changes in the laws and regulations affecting public companies, including the provisions of the Sarbanes-Oxley Act of 2002, rules adopted or proposed by the SEC and by NASDAQ and new accounting pronouncements will result in increased costs to us as we evaluate the implications of these laws, regulations and standards and respond to their requirements. To maintain high standards of corporate governance and public disclosure, we intend to invest substantial resources to comply with evolving standards. This investment will result in increased SG&A expenses and a diversion of management time and attention from strategic revenue generating and cost management activities. In addition, these new laws and regulations could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to

serve on our board of directors, on our board committees or as executive officers. We are taking steps to comply with the recently enacted laws and regulations in accordance with the deadlines by which compliance is required, but cannot predict or estimate the amount or timing of additional costs that we may

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incur to respond to their requirements, or if we will be able to timely comply with these recently enacted laws and regulations.

The price of our common shares could be adversely affected by the dilution caused by the sale of the common shares issued in our recently completed equity transaction

In December 2004, we sold 486,313 of our common shares to certain selling shareholders at a price of \$9.50 per share, issued warrants to purchase an additional 72,948 common shares at \$14.40 to those selling shareholders and issued warrants to purchase 21,316 common shares at \$14.40 to a placement agent, all as a result of the consummation of the share purchase agreement, dated as of December 23, 2004. These 580,577 common shares represent, assuming issuance of the 94,264 common shares underlying the warrants, 8.7% of our outstanding common shares. Sales of a substantial number of these common shares in the public market could depress the market price of our common shares. The perceived risk resulting from the sale of these common shares could cause some of our shareholders to sell their common shares, thus causing the price of our common shares to further decline. In addition, the downward pressure on the price of our common shares could cause some of our shareholders to engage in short sales of our common shares, which may cause the price of our common shares to decline even further.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk from changes in interest rates and foreign currency exchange rates since we fund our operations through short-term investments and have business transactions in Euros. A summary of our primary market risk exposures is presented below.

Interest Rate Risk

We have fixed income investments consisting of cash equivalents and short-term investments, which may be affected by changes in market interest rates. We do not use derivative financial instruments in our investment portfolio. We place our cash equivalents and short-term investments with high-quality financial institutions, limit the amount of credit exposure to any one institution and have established investment guidelines relative to diversification and maturities designed to maintain safety and liquidity. Investments are reported at amortized cost, which approximates fair value. A 1.0% change in interest rates during the year ended December 31, 2004 would have resulted in a \$40,000 change in our interest income during the year.

Foreign Currency Risk

Our foreign results of operations are subject to the impact of foreign currency fluctuations through both foreign currency transaction and foreign currency translation adjustments. We manage our risk to foreign currency transaction adjustments by maintaining foreign currency bank accounts in currencies in which we regularly transact business. We do not currently hedge against the risk of exchange rate fluctuations.

Our financial position and results of operations are impacted by translation adjustments caused by the conversion of foreign currency accounts and operating results into U.S. dollars for financial reporting purposes. A 1.0% fluctuation in the exchange rate between the U.S. dollar and the Euro at December 31, 2004 would have resulted in a \$24,000 change in the foreign currency translation amount recorded on our balance sheet, due to foreign currency translations. A 1.0% fluctuation in the average exchange rate between the U.S. dollar and the Euro for the year ended December 31, 2004 would have resulted in a \$35,000 change in our net income for the year ended December 31, 2004, due to foreign currency translations. During 2004 the average exchange rate between the Euro and the U.S. dollar increased by approximately 10%. The conversion of our foreign operations into U.S. dollars upon consolidation

resulted in net income that was approximately \$317,000 lower than would have been recorded had the exchange rate between the Euro and the U.S. dollar remained consistent with 2003 rates.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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| <u>Consolidated Balance Sheets at December 31, 2004 and 2003</u> | F-3 |
| <u>Consolidated Statements of Operations for each of the three years in the period ended December 31, 2004</u> | F-4 |
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Quarterly results of operations for the year ended December 31, 2004 are included in Note 15 of the Consolidated Financial Statements.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the chief executive officer and chief financial officer, of the design and operation of the Company's disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-14(e)) as of the end of the period covered by this Annual Report on Form 10-K. Based upon that evaluation, the Company's management, including the chief executive officer and chief financial officer, have concluded that, as of December 31, 2004, the Company's disclosure controls and procedures were effective to ensure that information required to be disclosed by the Company in the reports it files and submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Changes in Internal Controls

There were no changes in the Company's internal controls over financial reporting that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, the Company's internal controls over financial reporting.

ITEM 9B. OTHER INFORMATION

Shareholder Proposals for 2005 Annual Meeting

Historically, we have held our annual meeting of shareholders in the month of June. Our 2005 annual meeting of shareholders will be held on July 22, 2005.

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Any shareholder who meets the requirements of the proxy rules under the Exchange Act may submit proposals to our Board of Directors to be considered for submission to our annual meeting of shareholders to be held on July 22, 2005. Proposals should be submitted in writing by notice delivered or mailed by first-class United States mail, postage prepaid, to DATATRAK International, Inc., 6150 Parkland Boulevard, Suite 100, Mayfield Heights, Ohio 44124, Attention: President, and must be received no later than March 25, 2005. Any notice shall include: (a) the name and address of the shareholder and the text of the proposal to be introduced, (b) the number of common shares held of record, owned beneficially and represented by proxy by the shareholder as of the date of the notice and (c) a representation that the shareholder intends to appear in person or by proxy at the meeting to introduce the proposal specified in the notice. The chairman of the annual meeting may refuse to acknowledge the introduction of any shareholder proposal not made in compliance with the foregoing procedures.

Unless we receive notice of a shareholder proposal to be brought before the 2005 annual meeting by March 25, 2005, then we may use our discretion in voting proxies with respect to any shareholder proposal properly brought before such annual meeting.

2004 Private Placement

On December 28, 2004, we issued 486,313 common shares in connection with the consummation of a private placement to a total of ten purchasers at a purchase price of \$9.50 per common share. The terms of this financing included the issuance of three-year warrants to purchase a total of 72,948 common shares at \$14.40 per share to the investors in the private placement, and the issuance of three-year warrants to purchase a total of 21,316 common shares at \$14.40 per common share to placement agents for the private placement. The aggregate offering price of the 486,313 common shares was approximately \$4,620,000, and Stonegate Securities, Inc., the placement agent, was paid a commission of \$243,000 (equal to 5% of the aggregate offering price attributable to the placement agent), plus the warrants disclosed above, in connection with the private placement. We expect to use the proceeds of the private placement to expand our worldwide marketing and sales efforts, continue investing in software development, pay the fees associated with our alliance with SAS and for other general working capital purposes.

The sale of the common shares and the issuance of warrants in connection with the private placement were deemed to be exempt from registration under the Securities Act of 1933, as amended (the Securities Act), pursuant to an exemption or exemptions from registration under Section 4(2) of the Securities Act and/or Regulation D promulgated under the Securities Act.

Subsequently, on January 12, 2005 and in accordance with the terms and conditions of the Share Purchase Agreement entered into by and between the purchasers and us, we filed a Form S-3 Registration Statement with the Commission, to register the common shares and the common shares underlying the warrants. As of March 10, 2005, the Form S-3 Registration Statement had not been declared effective by the Commission. If the Form S-3 Registration Statement is not declared effective by May 12, 2005, we will be obligated to pay each purchaser 0.25% of the total purchase price paid by that purchaser for each week after that date that the Form S-3 Registration is not yet declared effective. In addition, we are prohibited from selling any of our common shares before March 25, 2005 at a price per common share of less than \$9.50 without paying the purchasers an amount equal to the difference between \$9.50 and the subsequent selling price, multiplied by the number of our common shares that each purchaser purchased in the December 2004 private placement.

Table of Contents**PART III****ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

The name, age and positions of each of our directors and executive officers are as follows:

| <u>Name</u> | <u>Age</u> | <u>Position</u> |
|----------------------|------------|---|
| Dr. Jeffrey A. Green | 49 | President, Chief Executive Officer and Director |
| Terry C. Black | 47 | Vice President of Finance, Chief Financial Officer, Treasurer and Assistant Secretary |
| Marc J. Shlaes | 50 | Vice President of Research and Development |
| Dr. Wolfgang Summa | 40 | Vice President of Global Operations |
| Timothy G. Biro | 51 | Director |
| Seth B. Harris | 64 | Director |
| Dr. Jerome H. Kaiser | 48 | Director |
| Dr. Mark J. Ratain | 50 | Director |
| Dr. Robert M. Stote | 65 | Director |

Jeffrey A. Green, Pharm.D., FCP. Dr. Green is our founder and has served as our President, Chief Executive Officer and a Director since March 1992. Prior to joining us in 1992, Dr. Green served as an Assistant Professor of Medicine and Radiology at Case Western Reserve University, Cleveland, Ohio. During his tenure at Case Western Reserve University, Dr. Green established and directed the Cardiovascular Clinical Pharmacology Research Program at University Hospitals of Cleveland, and was responsible for directing over 90 individual investigations during his tenure. Dr. Green has authored over 90 publications and has been an invited speaker at more than 170 national meetings.

Terry C. Black, MBA, CPA. Mr. Black has served as our Vice President of Finance and Chief Financial Officer since June 1994 and has served as our Treasurer and Assistant Secretary since January 1996. Prior to joining us, Mr. Black served in a variety of financial and accounting positions within the insurance replacement rental car industry.

Marc J. Shlaes, BB. Mr. Shlaes has served as our Vice President of Research and Development since December 2000. Mr. Shlaes is responsible for the development and testing of DATATRAK EDC and our related software offerings. Prior to December 2000, Mr. Shlaes also served as our Vice President and Managing Director of North America and as our Director of Technology and Services. Prior to joining us in 1998, Mr. Shlaes served in a variety of positions in the software development and delivery industry.

Wolfgang Summa, PhD., MSc. Dr. Summa has served as our Vice President of Global Operations since December 2000. Dr. Summa is responsible for our operational strategy including delivery of DATATRAK EDC® to customers. Prior to December 2000, Dr. Summa served as our Vice President and Managing Director of Europe and as our Manager of European Operations. Prior to joining us, Dr. Summa served in various research positions within the

EDC industry.

Timothy G. Biro, MBA. Mr. Biro has been a director since 1992. Mr. Biro has been the Managing Partner of Ohio Innovation Fund I, L.P., a venture capital firm, which invests in early-stage business, since 1997. Mr. Biro has been involved in venture capital financing since 1991. Prior to 1991, Mr. Biro was Superintendent of Pharmaceutical Manufacturing at Merck & Co., Inc.

Seth B. Harris. Mr. Harris has been a director since 1992, and has been the Chairman of Brand Development Ventures Inc., a consulting company that offers a wide range of services in new product development and marketing, since 2002. During 2000 and 2001, Mr. Harris was the Chairman of Toy Craze, Inc., a Cleveland based toy company. Mr. Harris was the Chairman of Frieder Inc., a distributor of consumer products, from 1993 to 2000. Prior to joining Frieder Inc., Mr. Harris was the President and Chief Executive Officer of Harris Wholesale, Inc., a wholesale pharmaceutical distribution company.

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Jerome H. Kaiser, Ph.D. Dr. Kaiser has been a director since December 1999. Dr. Kaiser is the Senior Vice President and director of Information Services for Rothschild, Inc., a private investment bank. Prior to his appointment to that position, Dr. Kaiser was a consultant to Rothschild, Inc. During 1998 and 1999, he was the Director of Product Management for Pfizer, Inc. From 1994 to 1998, Dr. Kaiser was employed by Hoffman-LaRoche, Inc.

Mark J. Ratain, M.D. Dr. Ratain has been a director since 1998. Dr. Ratain is a hematologist/oncologist and a clinical pharmacologist. He is a Professor of Medicine and Chairman of the Committee on Clinical Pharmacology and Pharmacogenomics and Associate Director for Clinical Science for the Cancer Research Center at the University of Chicago. Dr. Ratain has been associated with the Department of Medicine at the University of Chicago since 1983.

Robert M. Stote, M.D. Dr. Stote has been a director since 1993. Dr. Stote has served as the Senior Vice President and Chief Scientific Officer of Bentley Pharmaceuticals, Inc., a pharmaceutical company, since 1992. From 1993 until May 2004, Dr. Stote was also a director of Bentley Pharmaceuticals, Inc. Prior to joining Bentley Pharmaceuticals, Inc., Dr. Stote was employed for 20 years by SmithKline Beecham Corporation.

Terms of Directors

The number of Directors is currently fixed at seven. The Board of Directors is divided into two classes. The term of one class of Directors expires each year as follows: (1) Messrs. Biro and Kaiser and Drs. Stote and Green will serve until the 2005 annual meeting and (2) Dr. Ratain and Mr. Harris will serve until the 2006 annual meeting. One director seat in the class that will expire at the 2006 annual meeting is currently vacant.

Board of Directors and Corporate Governance Matters

During the last fiscal year, the Board of Directors met eleven times. No director attended fewer than 75% of the aggregate number of meetings of the Board of Directors and the committees on which each served during the period for which each was a member of the Board of Directors.

The Board of Directors has determined that all directors except Dr. Green, our President and Chief Executive Officer, are independent under the listing standards of the Nasdaq Stock Market. The independent directors intend to meet at least twice a year after regularly scheduled Board meetings in executive sessions. The sessions will be chaired by each of the Chairmen of the Audit, Compensation and Nominating and Corporate Governance Committees on a rotating basis. Any independent director can request that an additional session be scheduled. Our policy is that each member of the Board of Directors is expected to attend each annual meeting of shareholders.

The Board of Directors has an Audit Committee, a Compensation Committee, a Nominating Committee and Corporate Governance Committee and an Executive Committee. Set forth below is the current membership of each Board committee.

| Audit Committee | Compensation Committee | Nominating and Corporate Governance Committee | Executive Committee |
|----------------------------|-----------------------------------|--|--------------------------------|
| Mr. Biro (Chairman) | Mr. Harris (Chairman) | Dr. Kaiser (Chairman) | Dr. Green (Chairman) |
| Dr. Kaiser | Mr. Biro | Dr. Ratain | Mr. Biro |
| Dr. Ratain | Dr. Stote | Dr. Stote | Dr. Kaiser |

Audit Committee. The Audit Committee is responsible for the annual appointment of our auditors, with whom the Audit Committee reviews the scope of audit and non-audit assignments and related fees, the accounting principles we use in financial reporting, internal financial auditing procedures and the adequacy

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of internal control procedures. Specific functions and responsibilities of the Audit Committee are set forth in the Audit Committee Charter adopted by the Board of Directors. Our Board has determined that each of the members of the Audit Committee satisfies the current independence standards of the Nasdaq Stock Market listing standards and Section 10A(m)(3) of the Exchange Act, as amended. The Audit Committee met seven times in fiscal year 2004.

The Board also has determined that the Audit Committee Chairman, Timothy G. Biro, is an audit committee financial expert as that term is defined in Item 401(h) of Regulation S-K. As an audit committee financial expert, Mr. Biro satisfies the Nasdaq financial literacy and sophistication requirements.

Compensation Committee. The Compensation Committee has the authority to administer our stock option plans, including the selection of optionees and the timing of option grants, to review and monitor key employee compensation and benefits policies and to review and make recommendations to the Board regarding our senior management's yearly compensation levels. The Compensation Committee met twice during 2004.

Nominating and Corporate Governance Committee. In September 2004, the Board of Directors formed the Nominating and Corporate Governance Committee to replace the Nominating Committee. The purpose of the Nominating and Corporate Governance Committee is to (1) identify, select and recommend qualified individuals as nominees for the Board of Directors at each annual meeting or when otherwise required to fill a vacancy or increase the size of the Board of Directors and (2) assist the Board of Directors in developing and implementing the Company's corporate governance policies and guidelines. The Nominating and Corporate Governance Committee met three times during 2004.

Executive Committee. The Executive Committee has the authority to exercise all powers of the Board of Directors in the management of our business and affairs at any time when the entire Board of Directors cannot meet. The Executive Committee did not meet in 2004.

Shareholder Recommendations

The procedures by which shareholders may recommend nominees to the Board of Directors have not materially changed since those procedures were disclosed in the Company's proxy statement furnished to shareholders in connection with the Company's 2004 Annual Meeting of Shareholders.

Shareholder Communication with the Board

Shareholders may communicate their concerns directly to the entire Board or specifically to non-management directors of the Board by submitting in writing to us at the following address: Shareholder Communication, DATATRAK International, Inc., 6150 Parkland Boulevard, Suite 100, Mayfield Heights, Ohio 44124. The status of all outstanding concerns addressed to the entire Board or only non-management directors will be reported to the chair of the Audit Committee on a quarterly basis.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934 requires directors and certain of our executive officers and persons who beneficially own more than 10% of our common shares to file reports of ownership and changes in ownership on Forms 3, 4 and 5 with the Commission and Nasdaq. These people are further required to furnish us with copies of all such forms filed by them. Based solely on our review of the copies of the forms that we received, we believe that all of the Section 16(a) filing requirements were satisfied by our directors, executive officers and beneficial owners of more than 10% of our common shares.

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Code of Ethics

We have a code of ethics that applies to all directors, officers and employees of DATATRAK and its subsidiaries. Additionally, we have a separate code of ethics that applies solely to DATATRAK's principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions.

If we make any substantive amendments to or grant any waiver, including any implicit waiver, from a provision of our Code of Business Conduct and Ethics or Financial Code of Ethics to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions, we will disclose the nature of such amendment or waiver on our website or in a Current Report on Form 8-K.

ITEM 11. EXECUTIVE COMPENSATION

Compensation of Directors

Directors do not receive cash compensation for their service as members of our Board; rather, non-management directors are granted options to purchase our common shares as compensation for serving on the Board and its related committees. Directors also receive reimbursement for reasonable expenses incurred in attending meetings of the Board of Directors.

Under our current Amended and Restated Outside Director Stock Option Plan, each non-management director receives (1) an initial option grant to purchase 12,500 common shares at an exercise price equal to the fair market value of a share on the date of grant upon becoming a Board member, (2) an annual option grant to purchase 6,250 common shares at an exercise price equal to the fair market value of a share on the date of grant, and (3) 1,000 common shares to each non-management Chairman of a standing committee of the Board of Directors at an exercise price equal to the fair market value of a share on the date of grant. The annual grants occur automatically on the day of our annual shareholder meeting. Further, a retiring director who has served on our Board for at least five years and agrees to be available for limited consulting for a period of one year after his retirement receives a grant to purchase 6,250 common shares.

The Compensation Committee is evaluating the method in which we currently compensate our directors, and may recommend that we change the way in which directors are compensated. These changes could include granting restricted stock awards in lieu of options to purchase common shares or compensating our directors in the form of cash payments.

The following Report of the Compensation Committee on Executive Compensation and the performance graph included elsewhere in this Annual Report on Form 10-K do not constitute soliciting material and should not be deemed filed or incorporated by reference into any other Company filing under the Securities Act of 1933, as amended, or the Exchange Act except to the extent the Company specifically incorporates this Report or the performance graph by reference therein.

Report of the Compensation Committee on Executive Compensation

The Compensation Committee administers DATATRAK's stock option plans, including the selection of optionees and the timing of option grants, reviews and monitors key employee compensation and benefits policies and reviews and makes recommendations to the Board regarding DATATRAK's senior management yearly compensation levels. The members of the Compensation Committee during 2004 were Messrs. Harris and Biro and Dr. Stote, all of whom were non-employee Directors.

This report contains a discussion of the Board's compensation philosophy, together with a discussion of the factors considered by the Compensation Committee in determining the compensation of our President and Chief Executive Officer and the Named Executive Officers.

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Compensation Philosophy

The Board of Directors' compensation philosophy is that compensation paid to executive officers and other management personnel should consist of four elements: (1) salary, (2) annual incentive bonus, (3) stock options, and (4) welfare, retirement and other benefits. The compensation package is designed to attract and retain top quality management employees. To some extent, elements of compensation are designed to vary as DATATRAK's performance varies. In general, the elements of compensation that most typically have a significant relationship to the Company's performance are awards under the Company's stock option and bonus plans. The Committee's decisions concerning compensation make use of independent surveys of executive compensation of similarly situated companies.

Presented below is a discussion of the various components of the compensation arrangements provided to the Named Executive Officers, as well as a discussion of the compensation arrangements provided to DATATRAK's President and Chief Executive Officer.

2004 Compensation Decisions

Base Salary and Benefits. Salaries of executive officers are subject to minimum levels set by the terms of each executive's employment arrangement. The primary factor in setting salary levels pursuant to these arrangements was the desire to provide compensation in amounts sufficient to induce these individuals to either join or continue with the Company. Salary levels for executive officers reflect the Committee's judgments on appropriate salaries in light of the duties and responsibilities inherent in the executives' positions. The particular qualifications of an individual holding the position and his or her level of experience, as well as information concerning compensation paid by other companies in the industry, are considered in establishing salary levels. The Committee's assessment of the individual's performance and contribution to the Company's performance are the primary criteria influencing decisions regarding salary adjustments. During January 2003, as part of the Company's overall payroll cost savings plan, Dr. Green, Mr. Black, Mr. Shlaes and Dr. Summa each accepted a reduction in pay. Based on the Company's 2004 profitability and projections for continued growth and profitability in 2005, the salaries of the executive officers were reinstated at the end of 2004, and each of the Named Executive Officers was granted a pay increase. Dr. Green's new salary is \$210,000 annually. Mr. Black's new salary is \$150,000 annually. Mr. Shlaes's new salary is \$152,000 annually. Dr. Summa's new salary is 165,850 Euro annually.

Stock Options. DATATRAK uses stock options as a long-term incentive program for its executive officers. Stock options are used because they directly relate the amounts earned by the executive officers to the amount of appreciation realized by the Company's shareholders over comparable periods. Stock options also provide executive officers with the opportunity to acquire and build a meaningful ownership interest. The Committee considers stock option awards throughout the year. In determining the number of options awarded to an individual executive officer, the Committee generally establishes a level of award based upon the position of the individual and his or her level of responsibility, and upon recommendations made by the President and Chief Executive Officer. The Committee's decisions concerning individual option awards are based on its judgment concerning the appropriate amount of long-term compensation that should be paid to the executive in question. The Company awarded 27,000 such stock options to executives during 2004. A total of 96,000 stock options were awarded to employees, including the Named Executive Officers, during 2004.

Bonuses. DATATRAK may pay additional compensation in the form of discretionary bonuses to executive officers. The bonus amount in any given year is determined by the Compensation Committee, taking into account several factors, including the executive officer's salary and position, the executive officer's performance and the Company's overall performance. Bonuses may be provided either in the form of cash, common shares or a combination of the two, as the Compensation Committee determines. Mr. Black and Mr. Shlaes each received a

\$10,000 bonus in 2004. No other bonuses were paid to the Named Executive Officers in 2004.

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President and Chief Executive Officer Compensation. Dr. Green's employment contract contemplates compensation in two broad areas: (1) a base salary and (2) stock options under a long-term compensation plan. During December 2004, Dr. Green was granted an increase in his annual salary from \$170,000 to \$210,000. Of this increase, \$30,000 represented a reinstatement to his 2002 salary level, and \$10,000 represented a pay increase. Dr. Green was awarded options to purchase 12,000 common shares in 2004. Dr. Green did not receive a bonus in 2004.

THE COMPENSATION COMMITTEE

Seth B. Harris (Chairman)
Timothy G. Biro
Dr. Robert M. Stote

Compensation Committee Interlocks and Insider Participation

There were no compensation committee interlocks or insider participation activities in 2004.

Summary Compensation Table

The table below sets forth certain information concerning the annual or long-term compensation for services in all capacities, during the fiscal years ended December 31, 2004, 2003 and 2002, to our Chief Executive Officer and our three other executive officers whose annual salary and bonus exceeded \$100,000 (the Named Executive Officers).

| Name and Principal Position | Year | Annual Compensation | | Long-Term Compensation Awards Securities | All Other Compensation (2) |
|---|------|---------------------|--------|---|-------------------------------|
| | | Salary | Bonus | Underlying Options/SARs | |
| Dr. Jeffrey A. Green President, Chief Executive Officer and Director | 2004 | \$ 176,540 | \$ | 12,000 (3) | \$ |
| | 2003 | 172,310 | | 11,000 (3) | |
| | 2002 | 198,850 | | 22,500 (3) | |
| Terry C. Black Vice President of Finance, Chief Financial Officer, Treasurer and Assistant Secretary | 2004 | 123,580 | 10,000 | 5,000 (4) | |
| | 2003 | 120,620 | | 7,000 (4) | |
| | 2002 | 139,130 | | 7,813 (4) | |
| Marc J. Shlaes Vice President of Research and Development | 2004 | 127,990 | 10,000 | 5,000 (5) | |
| | 2003 | 124,920 | | 7,000 (5) | |
| | 2002 | 142,980 | 19,460 | 6,875 (5) | |
| Dr. Wolfgang Summa | 2004 | 170,880(6) | | 5,000 (7) | |

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| | | | |
|--------------------------|------|---------|------------|
| Vice President of Global | 2003 | 154,770 | 7,000 (7) |
| Operations | 2002 | 153,400 | 18,875 (7) |

- (1) No Named Executive Officer received perquisites or other personal benefits in excess of the lesser of \$50,000 or 10% of that individual's salary plus annual bonus. No long-term incentive plan payouts or restricted stock awards have been made to any of the Named Executive Officers.
- (2) No other compensation was received by the Named Executive Officers.
- (3) Dr. Green's options were granted as follows: (1) 22,500 on June 4, 2002, at an exercise price of \$2.78 per share, 50% of which became exercisable on June 4, 2004 and 50% of which will

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become exercisable on June 4, 2006, (2) 10,000 on December 23, 2003, at an exercise price of \$6.07 per share, 50% of which will become exercisable on December 23, 2005 and 50% of which will become exercisable on December 23, 2007, (3) 1,000 on December 23, 2003, at an exercise price of \$6.07 per share, 50% of which became exercisable on December 23, 2004 and 50% of which will become exercisable on December 23, 2005 and (4) 12,000 on December 28, 2004, at an exercise price of \$11.02 per share, 50% of which will become exercisable on December 28, 2006 and 50% of which will become exercisable on December 28, 2008.

- (4) Mr. Black's options were granted as follows: (1) 7,813 on June 4, 2002, at an exercise price of \$2.78 per share, 50% of which became exercisable on June 4, 2004 and 50% of which will become exercisable on June 4, 2006, (2) 6,000 on December 23, 2003, at an exercise price of \$6.07 per share, 50% of which will become exercisable on December 23, 2005 and 50% of which will become exercisable on December 23, 2007, (3) 1,000 on December 23, 2003, at an exercise price of \$6.07 per share, 50% of which became exercisable on December 23, 2004 and 50% of which will become exercisable on December 23, 2005 and (4) 5,000 on December 28, 2004, at an exercise price of \$11.02 per share, 50% of which will become exercisable on December 28, 2006 and 50% of which will become exercisable on December 28, 2008.
- (5) Mr. Shlaes's options were granted as follows: (1) 6,875 on June 4, 2002, at an exercise price of \$2.78 per share, 50% of which became exercisable on June 4, 2004 and 50% of which will become exercisable on June 4, 2006, (2) 6,000 on December 23, 2003, at an exercise price of \$6.07 per share, 50% of which will become exercisable on December 23, 2005 and 50% of which will become exercisable on December 23, 2007, (3) 1,000 on December 23, 2003, at an exercise price of \$6.07 per share, 50% of which became exercisable on December 23, 2004 and 50% of which will become exercisable on December 23, 2005 and (4) 5,000 on December 28, 2004, at an exercise price of \$11.02 per share, 50% of which will become exercisable on December 28, 2006 and 50% of which will become exercisable on December 28, 2008.
- (6) Dr. Summa's 2004 salary was 136,700 Euro. Based on the average exchange rate between the United States dollar and the Euro during 2004, Dr. Summa's 2004 salary of 136,700 Euro was the equivalent of \$170,880.
- (7) Dr. Summa's options were granted as follows: (1) 18,875 on June 4, 2002, at an exercise price of \$2.78 per share, 50% of which became exercisable on June 4, 2004 and 50% of which will become exercisable on June 4, 2006, (2) 6,000 on December 23, 2003, at an exercise price of \$6.07 per share, 50% of which will become exercisable on December 23, 2005 and 50% of which will become exercisable on December 23, 2007, (3) 1,000 on December 23, 2003, at an exercise price of \$6.07 per share, 50% of which became exercisable on December 23, 2004 and 50% of which will become exercisable on December 23, 2005 and (4) 5,000 on December 28, 2004, at an exercise price of \$11.02 per share, 50% of which will become exercisable on December 28, 2006 and 50% of which will become exercisable on December 28, 2008.

Table of Contents**Option Grants in Last Fiscal Year**

The table below sets forth certain information concerning grants of stock options made during the year ended December 31, 2004 to the Named Executive Officers. Such grants are reflected in the Summary Compensation Table above.

| Name | Individual Grants | | | Exercise or Base Price (\$/Sh) | Expiration Date | Potential Realizable Value at Assumed Annual Rates of Stock Price Appreciation for Option Term (3) | |
|----------------------|---|--|--|--------------------------------|-----------------|--|------------|
| | Number of Securities Underlying Options Granted (1) | % of Total Options Granted to Employees in Fiscal Year (2) | | | | 5% (\$) | 10% (\$) |
| Dr. Jeffrey A. Green | 12,000 | 13% | | \$ 11.02 | 12/28/14 | \$ 83,165 | \$ 210,757 |
| Terry C. Black | 5,000 | 5 | | 11.02 | 12/28/14 | 34,652 | 87,815 |
| Marc J. Shlaes | 5,000 | 5 | | 11.02 | 12/28/14 | 34,652 | 87,815 |
| Dr. Wolfgang Summa | 5,000 | 5 | | 11.02 | 12/28/14 | 34,652 | 87,815 |

- (1) All options were awarded at an exercise price equal to the fair market value of our common shares on the date of grant.
- (2) Based on an aggregate of 96,000 options granted to employees under our Amended and Restated 1996 Key Employees and Consultants Stock Option Plan, including the Named Executive Officers.
- (3) Potential realizable value is based upon certain assumed rates of appreciation pursuant to rules prescribed by the Commission, and do not represent an estimate of the future stock price growth in our common shares. Actual gains, if any, on stock option exercises are dependent on the future performance of our common shares. There can be no assurance that the amounts reflected in this table will be achieved.

Option Exercises and Fiscal Year-End Option Values

The table below shows information with respect to the exercise of options to purchase common shares by the Named Executive Officers and unexercised options to purchase common shares for the Named Executive Officers as of December 31, 2004.

**Aggregate Option Exercises in Last Fiscal Year
And December 31, 2004 Option Value**

| Name | Stock Acquired on Exercise | Value Realized | Number of Securities Underlying Unexercised Options at | | Value of Unexercised In-the-Money Options at | |
|----------------------|----------------------------|----------------|--|----------------------|--|----------------------|
| | | | December 31, 2004 | December 31, 2004(1) | December 31, 2004(2) | December 31, 2004(1) |
| Dr. Jeffrey A. Green | | \$ | 151,750 | 33,750 | \$ 928,153 | \$ 143,153 |

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| | | | | | | |
|--------------------|--------|--------|--------|--------|---------|---------|
| Terry C. Black | 5,000 | 36,750 | 60,657 | 15,406 | 334,110 | 63,632 |
| Marc J. Shlaes | 12,500 | 57,750 | 60,938 | 14,937 | 433,728 | 59,800 |
| Dr. Wolfgang Summa | 12,500 | 90,875 | 54,938 | 20,937 | 405,348 | 108,820 |

- (1) Options are in-the-money if the market value of our common shares exceeds the exercise price.
- (2) Represents the total gain which would be realized if all in-the-money options beneficially held at December 31, 2004 were exercised, determined by multiplying the number of common shares

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underlying the options by the difference between the per share option exercise price and \$10.95, the closing price for our common shares as reported by Nasdaq on December 31, 2004.

Equity Compensation Plan Information

The following table sets forth information concerning common shares authorized or available for issuance under our equity compensation plans as of the December 31, 2004.

| Plan Category | Number of Securities to be | | 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)) |
|---|--|-----|---|---|
| | Issued Upon Exercise of Outstanding Options, Warrants and Rights | (a) | | |
| Equity compensation plans approved by shareholders | 1,325,967 | \$ | 4.96 | 188,775 |
| Equity compensation plans not approved by shareholders(1) (2) | 106,889 | \$ | 13.27 | |
| Total | 1,432,856 | \$ | 5.58 | 188,775 |

(1) The terms of our August 2003 private placement of 602,500 common shares required the issuance of warrants to purchase common shares at \$4.80 per share as payment for services performed by certain placement agents related to our private placement. 12,625 of these warrants were outstanding at December 31, 2004. The warrants are fully vested as of the date of grant and expire August 8, 2008.

(2) The terms of our December 2004 private placement of 486,313 common shares required the issuance of warrants to purchase a total of 21,316 common shares at \$14.40 per share as payment for services performed by certain placement agents related to our private placement. In addition, the private placement required the issuance of warrants to purchase a total of 72,948 common shares at \$14.40 per share to the investors who participated in our private placement. The warrants, all of which were outstanding at December 31, 2004, are fully vested as of the date of grant and expire December 23, 2007.

Employment Agreements

Dr. Jeffrey A. Green. In February 2001, we entered into an employment agreement with Dr. Green providing for an initial term of one year. This agreement, which remains in effect, automatically renews for successive one-year periods thereafter unless certain prior notice requirements are satisfied. The base salary initially provided for in this agreement is \$180,000 per year, to be reviewed at least annually by the Compensation Committee. Currently the base salary provided for Dr. Green pursuant to this agreement is \$210,000 for 2005. Bonuses may be paid to Dr. Green at

the discretion of the Compensation Committee. The agreement also provides Dr. Green with the right to participate in all benefit plans made available to our executives and/or employees. Dr. Green's employment may be terminated with or without cause, upon his death or disability or with sufficient reason. Additionally, under this agreement, Dr. Green is entitled to terminate his employment for good reason. Good reason for such termination will exist if at any time, (1) there is a material breach of Dr. Green's employment agreement by the Company, (2) shareholders fail to elect Dr. Green to the Board of Directors or Dr. Green is otherwise removed from the Board of Directors, and (3) except in connection with the termination of Dr. Green's employment in strict compliance with the terms of the agreement, the Board of Directors (a) fails to elect Dr. Green to his current executive position, (b) fails to vest Dr. Green with the powers and authority customarily associated with his current position or (c) significantly diminishes his responsibilities, duties, power or authority. If Dr. Green terminates his employment for good reason, he will be entitled to continue to receive his base salary for two years following the date of such termination. If Dr. Green's employment is terminated in connection with a sale of our business, he will be entitled to continue to receive his base salary for one year following the date of such termination. If his employment is terminated without cause or without sufficient

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reason, he will be entitled to continue to receive his base salary for a period of two years subsequent to the date of termination. If Dr. Green terminates his employment without good reason, or if he is terminated for cause, then he will be entitled to receive his base salary through the date of termination. For purposes of Dr. Green's agreement, cause is defined as a determination by the Board of Directors that the employee was (1) convicted of a felony involving moral turpitude or a felony in connection with his employment, (2) engaged in fraud, embezzlement, material willful destruction of property or material disruption of our operations, (3) using or in possession of illegal drugs and/or alcohol on our premises or reporting to work under the influence of same, or (4) engaged in conduct, in or out of the workplace, which in our reasonable determination has an adverse effect on our reputation or business. Sufficient reason shall mean a good faith determination that the employee failed to adequately perform his duties as an officer or achieve the business objectives mutually agreed upon by the parties. Dr. Green also agreed to certain noncompetition and nondisclosure provisions, which under certain conditions continue for a period of up to twenty-four months following a termination of Dr. Green's employment.

Terry C. Black. In February 2001, we entered into an employment agreement with Mr. Black providing for an initial term of one year. This agreement, which remains in effect, automatically renews for successive one-year periods thereafter unless certain prior notice requirements are satisfied. The base salary initially provided for in this agreement is \$125,000 per year, to be reviewed at least annually by the Compensation Committee. Currently the base salary provided for Mr. Black pursuant to this agreement is \$150,000 for 2005. Bonuses may be paid to Mr. Black at the discretion of the Compensation Committee. The agreement also provides Mr. Black with the right to participate in all benefits plans made available to our executives and/or employees. Mr. Black's employment may be terminated with or without cause or upon his death or disability. Additionally, Mr. Black is entitled to terminate his employment for good reason. If Mr. Black terminates his employment for good reason, he will be entitled to receive his base salary for a period of one year following the date of such termination. If Mr. Black's employment is terminated in connection with a sale of our business, he will be entitled to continue to receive his base salary for one year following the date of such termination. If his employment is terminated without cause, he will be entitled to receive his base salary for a period of one year subsequent to the date of termination. If Mr. Black terminates his employment without good reason, or if he is terminated for cause, he will be entitled to receive his base salary through the date of termination. For purposes of Mr. Black's agreement, cause is defined as a determination by the Board of Directors that the employee was (1) convicted of a felony involving moral turpitude or a felony in connection with his employment, (2) engaged in fraud, embezzlement, material willful destruction of property or material disruption of our operations, (3) using or in possession of illegal drugs and/or alcohol on our premises or reporting to work under the influence of same, or (4) engaged in conduct, in or out of the workplace, which in our reasonable determination has an adverse effect on our reputation or business. Mr. Black also agreed to certain noncompetition and nondisclosure provisions, which continue under certain conditions for a period up to eighteen months following a termination of Mr. Black's employment.

Dr. Wolfgang Summa. In December 2000, Dr. Summa signed an employment agreement with our German subsidiary, DATRAK Deutschland GmbH, providing for an initial term of four years. This agreement, which remains in effect, automatically renews for successive one-year periods thereafter unless certain prior notice requirements are satisfied. The base salary initially provided for in this agreement is 107,370 Euro (approximately \$110,000) per year, to be reviewed at least annually by the Compensation Committee. Currently the base salary provided for Dr. Summa pursuant to this agreement is 165,850 Euro for 2005. Bonuses may be paid to Dr. Summa at the discretion of the Compensation Committee. The agreement also provides Dr. Summa with the right to participate in all benefits plans made available to our executives and/or employees. Dr. Summa's employment may be terminated with or without cause or upon his death or disability. Additionally, Dr. Summa is entitled to terminate his employment for good reason. If Dr. Summa terminates his employment for good reason, he will be entitled to receive his base salary for a period of one year following the date of such termination. If Dr. Summa's employment is terminated in connection with the sale of our business, he will be entitled to continue to receive his base salary for one year following the date of such termination. If his employment is terminated without cause, he will be entitled to receive his base salary for a

period of one year subsequent to the date of termination. If Dr. Summa terminates his employment without good reason, or if he is terminated for cause, he will be entitled to receive his base salary through the date of termination. For purposes of Dr. Summa's

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agreement, *cause* is defined as a determination by the Board of Directors that the employee was (1) convicted of a felony involving moral turpitude or a felony in connection with his employment, (2) engaged in fraud, embezzlement, material willful destruction of property or material disruption of our operations, (3) using or in possession of illegal drugs and/or alcohol on our premises or reporting to work under the influence of same, or (4) engaged in conduct, in or out of the workplace, which in our reasonable determination has an adverse effect on our reputation or business. Dr. Summa also agreed to certain noncompetition and nondisclosure provisions, which continue under certain conditions for a period up to eighteen months following a termination of Dr. Summa's employment. The agreement is governed by German law.

Marc J. Shlaes. In March 2003, we entered into an employment agreement with Mr. Shlaes providing for an initial term of one year. This agreement, which remains in effect, automatically renews for successive one-year periods thereafter unless certain prior notice requirements are satisfied. The base salary initially provided for in this agreement is \$145,000 per year, to be reviewed at least annually by the Compensation Committee. Currently the base salary provided for Mr. Shlaes pursuant to this agreement is \$152,000 for 2005. Bonuses may be paid to Mr. Shlaes at the discretion of the Compensation Committee. The agreement also provides Mr. Shlaes with the right to participate in all benefits plans made available to our executives and/or employees. Mr. Shlaes's employment may be terminated with or without cause or upon his death or disability. Additionally, Mr. Shlaes is entitled to terminate his employment for any or no reason. If Mr. Shlaes voluntarily terminates his employment, all obligations under his employment will cease to exist. If Mr. Shlaes's employment is terminated in connection with the sale of our business, he will be entitled to continue to receive his base salary for one year following the date of such termination. If his employment is terminated without cause, he will be entitled to receive his base salary for a period of one year subsequent to the date of termination. If Mr. Shlaes is terminated for *cause*, he will be entitled to receive his base salary through the date of termination. For purposes of Mr. Shlaes's agreement, *cause* is defined as a determination by the Board of Directors that the employee (1) fails to complete satisfactorily our routine pre-employment background check, (2) was convicted of a felony involving moral turpitude or a felony in connection with his employment, (3) was engaged in fraud, embezzlement, material willful destruction of property or material disruption of our operations, (4) was using or in possession of illegal drugs and/or alcohol on our premises or reporting to work under the influence of same, or (5) was engaged in conduct, in or out of the workplace, which in our reasonable determination has an adverse effect on the our reputation or business. Mr. Shlaes also agreed to certain noncompetition and nondisclosure provisions, which continue under certain conditions for a period up to fifteen months following a termination of Mr. Shlaes's employment.

Table of Contents**Performance Graph**

The following line graph compares the yearly cumulative total shareholder return on our common shares against the cumulative total return of the Nasdaq Stock Market U.S. Index and the Nasdaq Health Services Index for the period commencing December 31, 1999 and ending December 31, 2004. The graph assumes that the value of the investment in our common shares and each index was \$100 on December 31, 1999, and that all dividends, if any, were reinvested.

| | 12/31/99 | 12/31/00 | 12/31/01 | 12/31/02 | 12/31/03 | 12/31/04 |
|------------------------|----------|----------|----------|----------|----------|----------|
| DATATRAK | 100 | 77.60 | 73.10 | 47.45 | 166.90 | 307.03 |
| Nasdaq US | 100 | 60.30 | 45.49 | 26.40 | 38.36 | 40.51 |
| Nasdaq Health Services | 100 | 78.33 | 83.23 | 75.37 | 95.63 | 112.45 |

Table of Contents**ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT**

The following table shows, as of February 28, 2005, unless otherwise indicated, the beneficial ownership of our common shares of (1) each person who is known to us to own beneficially more than 5% of our outstanding common shares, (2) each of our directors, (3) each of the Named Executive Officers and (4) all directors and Named Executive Officers as a group. Unless otherwise indicated, all information with respect to beneficial ownership has been furnished by each director or Named Executive Officer, or 5% holder, as the case may be.

| Name and Address of Beneficial Owner (1) | Common Shares Beneficially Owned (2) | |
|---|---|---------|
| | Number | Percent |
| Timothy G. Biro (3) | 64,200 | * |
| Terry C. Black | 70,657 | 1.0% |
| Dr. Jeffrey A. Green (4) | 380,974 | 5.5% |
| Seth B. Harris (5) | 263,434 | 3.8% |
| Dr. Jerome H. Kaiser | 64,600 | * |
| Dr. Mark J. Ratain | 81,000 | 1.2% |
| Marc J. Shlaes | 60,938 | * |
| Dr. Robert M. Stote | 106,853 | 1.6% |
| Dr. Wolfgang Summa | 54,938 | * |
| FMR Corp. (6) | 621,645 | 9.2% |
| 82 Devonshire Street Boston, Massachusetts 02109 | | |
| All directors and Named Executive Officers as a group (9 persons) | 1,147,594 | 15.5% |

* Less than one percent.

- (1) The address of the directors and executive officers listed above is c/o DATATRAK International, Inc., 6150 Parkland Boulevard, Suite 100, Mayfield Heights, Ohio 44124.
- (2) The number of common shares deemed outstanding includes (1) 6,770,148 common shares outstanding as of February 28, 2005 and (2) with respect to each of the following individuals and groups, the following number of common shares, which may be purchased pursuant to option exercises within 60 days after February 28, 2005: Mr. Biro (63,000 common shares); Mr. Black (50,657 common shares); Dr. Green (126,750 common shares); Mr. Harris (77,000 common shares); Dr. Kaiser (60,000 common shares); Dr. Ratain (74,000 common shares); Mr. Shlaes (55,938 common shares); Dr. Stote (64,500 common shares); Dr. Summa (39,938 common shares); and all directors and Named Executive Officers as a group (611,783 common shares).
- (3) Includes 200 common shares held by Mr. Biro's wife.
- (4) Includes 73,969 common shares held by Dr. Green's wife and 500 shares held by Dr. Green's son. Dr. Green disclaims beneficial ownership of these 74,469 common shares.
- (5) Includes 44,634 common shares held in trust for Mr. Harris.
- (6) Various persons have the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of, our common shares. The interest of one person, Fidelity Small Cap Stock Fund, an investment company registered under the Investment Company Act of 1940, in our common shares, amounted to 570,345

shares or 8.4% of the total common shares outstanding at February 28, 2005. The information provided herein, with respect to the beneficial ownership of

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our common shares by FMR Corp., was obtained solely from the Schedule 13-G filed with Commission on January 10, 2005 by FMR Corp.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

As a result of our December 2004 private placement, we are a party to a share purchase agreement that grants registration rights to the purchasers of our common shares issued in the private placement. Under the terms of the share purchase agreement, the holders of an aggregate of 486,313 our common shares, along with the holders of 94,264 warrants to purchase our common shares, require us to register such shares, at our expense, under the Securities Act prior to May 12, 2005. The holders of the shares purchased in the private placement are permitted to participate, at our expense, in any other registration of our common shares under the Securities Act, until such time as the shares purchased in the private placement are registered under the Securities Act.

In the private placement, Fidelity Securities Fund: Fidelity Small Cap Growth Fund (the Fidelity Growth Fund) purchased 10,000 of our common shares and received 1,500 warrants to purchase common shares. The Fidelity Growth Fund is a wholly-owned subsidiary of FMR Corp. and an affiliate of Fidelity Small Cap Stock Fund.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**Independent Auditors**

The Audit Committee has appointed Ernst & Young LLP to continue as our independent auditors for our fiscal year ending December 31, 2005. Set forth below are the aggregate fees and out of pocket expenses billed (or expected to be billed with respect to 2004), on a consolidated basis, by Ernst & Young LLP for providing the services indicated for the fiscal years ended December 31, 2004 and December 31, 2003:

| | Year End December 31, 2004 | Year End December 31, 2003 |
|------------------------|---|---|
| Audit fees (1) | \$ 164,887 | \$ 158,425 |
| Audit related fees (2) | 5,491 | |
| Tax fees (3) | 30,800 | 20,601 |
| All Other Fees (4) | 5,000 | |
| Total | \$ 206,178 | \$ 179,026 |

- (1) Includes fees and expenses related to the fiscal year audit and the interim reviews, notwithstanding when the fees and expenses were billed or when the services were rendered.
- (2) Includes fees and expenses for services related to the Sarbanes-Oxley Act of 2002.
- (3) Includes fees and expenses for services relating to tax preparation and planning.
- (4) Includes fees and expenses for services rendered from January through December of the fiscal year, related to accounting for stock compensation equity plans, notwithstanding when the fees and expenses were billed.

Representatives of Ernst & Young LLP are expected to be present at our annual meeting. They will have the opportunity to make a statement if they so desire, and are expected to be available to respond to appropriate questions.

Pre-Approval of Policies and Procedures

The Audit Committee has adopted a policy that requires advance approval of all audit and non-audit services provided by our independent auditor prior to the engagement of the independent auditor with respect to such services. The Chairman of the Audit Committee has been delegated the authority by the Audit Committee to evaluate and pre-approve the engagement of the independent auditors when the entire Audit Committee is unable to do so. The Chairman must report all such pre-approvals to the entire Audit Committee at the next committee meeting.

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All of the services described above for our 2004 fiscal year were pre-approved by the Audit Committee.

The following Report of the Audit Committee does not constitute soliciting material and should not be deemed filed or incorporated by reference into any other Company filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent the Company specifically incorporates this Report by reference therein.

Report of the Audit Committee

The Audit Committee oversees DATATRAK's financial reporting process on behalf of the Board of Directors. The Audit Committee's activities are governed by a written charter adopted by the Board of Directors

Management has the primary responsibility for DATATRAK's financial statements and the reporting process, including the system of internal controls. The independent auditors audit the annual financial statements prepared by management and express an opinion on the conformity of those financial statements with accounting principles generally accepted in the United States. The Audit Committee monitors these processes.

In this context, the Audit Committee met and held discussions with management and the independent auditors. Management represented to the Audit Committee that DATATRAK's financial statements were prepared in accordance with accounting principles generally accepted in the United States, and the Audit Committee reviewed and discussed the audited financial statements with management and the independent auditors, including a discussion of the quality, not just the acceptability, of the accounting principles, the reasonableness of specific judgments and the clarity of disclosures in the financial statements. The Audit Committee also discussed with the independent auditors such other matters as are required to be discussed with the Audit Committee by Statement on Auditing Standards No. 61 (*Communications with Audit Committees*), as amended by Statement on Auditing Standards No. 90 (*Audit Committee Communications*).

In addition, the independent auditors provided to the Audit Committee the written disclosures and letter required by Independence Standards Board Standard No. 1 (*Independence Discussions With Audit Committees*), related to the auditors' independence. The Audit Committee discussed with the independent auditors the auditors' independence from the Company and management and considered the compatibility of nonaudit services with the auditors' independence.

The Audit Committee discussed with DATATRAK's financial management and independent auditors the overall scope and plans for the audit. The Audit Committee also met with the independent auditors, with and without management present, to discuss the results of the examinations, their evaluation of the Company's internal controls and the overall quality of our financial reporting. In addition, the Audit Committee considered other areas of its oversight relating to the financial reporting process that it determined appropriate.

Based on the reviews and discussions referred to above, the Audit Committee recommended to the Board of Directors, and the Board of Directors has approved, that the audited financial statements be included in the Company's Annual Report on Form 10-K for the year ended December 31, 2004 for filing with the Securities and Exchange Commission.

THE AUDIT COMMITTEE

Timothy G. Biro (Chairman)
Dr. Jerome H. Kaiser
Dr. Mark J. Ratain

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(1) Financial Statements

See Item 8 of Part II of this Annual Report on Form 10-K.

(2) Financial Statement Schedules

All financial statement schedules for DATATRAK and its subsidiaries have been included in the consolidated financial statements or the related footnotes, or such schedules are either inapplicable or not required.

(3) Exhibits

See the Index to Exhibits at page E-1 of this Annual Report on Form 10-K.

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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.

DATATRAK INTERNATIONAL, INC.

/s/ Jeffrey A. Green

Jeffrey A. Green
President and Chief Executive Officer

Date: March 11, 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.

| Signature | Title |
|---|---|
| <u>/s/ Jeffrey A. Green</u> Jeffrey A. Green | President and Chief Executive Officer and Director (Principal Executive Officer) |
| <u>/s/ Terry C. Black</u> Terry C. Black | Vice President of Finance, Chief Financial Officer and Treasurer and Assistant Secretary (Principal Financial and Accounting Officer) |
| <u>/s/ Timothy G. Biro</u> Timothy G. Biro | Director |
| <u>/s/ Seth B. Harris</u> Seth B. Harris | Director |
| <u>/s/ Robert M. Stote</u> Robert M. Stote | Director |
| <u>/s/ Jerome H. Kaiser</u> Jerome H. Kaiser | Director |
| <u>/s/ Mark J. Ratain</u> Mark J. Ratain | Director |

Date: March 11, 2005

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders
DATATRAK International, Inc.

We have audited the accompanying consolidated balance sheets of DATATRAK International, Inc. and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2004. 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 consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of DATATRAK International, Inc. and subsidiaries at December 31, 2004 and 2003, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles.

ERNST & YOUNG LLP

Cleveland, Ohio
February 2, 2005

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Table of Contents**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES****CONSOLIDATED BALANCE SHEETS**

| | December 31, | |
|--|---------------------|--------------|
| | 2004 | 2003 |
| Assets | | |
| Current assets | | |
| Cash and cash equivalents | \$ 2,232,276 | \$ 1,727,335 |
| Short-term investments | 5,686,957 | 2,533,849 |
| Restricted cash | | 23,979 |
| Accounts receivable, net | 1,989,948 | 788,342 |
| Prepaid expenses and other receivables | 488,505 | 170,552 |
| Total current assets | 10,397,686 | 5,244,057 |
| Property and equipment | | |
| Equipment | 5,299,820 | 5,324,071 |
| Leasehold improvements | 614,507 | 604,322 |
| | 5,914,327 | 5,928,393 |
| Less accumulated depreciation | 4,491,563 | 4,909,654 |
| | 1,422,764 | 1,018,739 |
| Other assets | | |
| Restricted cash | 80,611 | 74,189 |
| Deposit | 39,549 | 39,549 |
| | 120,160 | 113,738 |
| Total assets | \$ 11,940,610 | \$ 6,376,534 |

Liabilities and Shareholders Equity

| | | |
|---|------------|------------|
| Current liabilities | | |
| Accounts payable | \$ 185,974 | \$ 170,740 |
| Current portion of capital lease obligation | | 23,979 |
| Accrued expenses | 1,052,301 | 683,846 |
| Deferred revenue | 584,857 | 897,138 |
| Total current liabilities | 1,823,132 | 1,775,703 |

Shareholders equity

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Serial Preferred Shares, without par value; authorized 1,000,000 shares; none issued

Common shares, without par value, authorized 25,000,000 shares as of December 31, 2004 and December 31, 2003; issued 9,915,895 shares as of December 31, 2004 and 9,306,053 shares as of December 31, 2003; outstanding 6,615,895 shares as of December 31, 2004 and 6,006,053 as of December 31, 2003

| | | |
|--|---------------|--------------|
| Treasury shares, 3,300,000 shares at cost | 60,584,110 | 56,458,996 |
| Common share warrants | (20,188,308) | (20,188,308) |
| Accumulated deficit | 711,872 | 135,424 |
| Foreign currency translation | (30,963,636) | (31,780,670) |
| | (26,560) | (24,611) |
| Total shareholders' equity | 10,117,478 | 4,600,831 |
| Total liabilities and shareholders' equity | \$ 11,940,610 | \$ 6,376,534 |

See accompanying notes.

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Table of Contents**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF OPERATIONS**

| | For the Year Ended December 31, | | |
|--|--|----------------|----------------|
| | 2004 | 2003 | 2002 |
| Revenue | \$ 11,305,112 | \$ 7,052,158 | \$ 4,720,912 |
| Direct costs | 2,633,805 | 1,622,231 | 1,803,671 |
| Gross profit | 8,671,307 | 5,429,927 | 2,917,241 |
| Selling, general and administrative expenses | 7,229,433 | 5,550,833 | 7,893,208 |
| Special items | | | 363,964 |
| Depreciation and amortization | 650,961 | 936,958 | 1,122,528 |
| Income (loss) from operations | 790,913 | (1,057,864) | (6,462,459) |
| Other income (expense): | | | |
| Interest income | 42,927 | 25,596 | 89,196 |
| Interest expense | (203) | (6,701) | (17,347) |
| Other income (expense) | (8,103) | (5,336) | |
| Income (loss) before income taxes | 825,534 | (1,044,305) | (6,390,610) |
| Income tax expense | 8,500 | 4,316 | |
| Net income (loss) | \$ 817,034 | \$ (1,048,621) | \$ (6,390,610) |
| Net income (loss) per share: | | | |
| Basic: | | | |
| Net income (loss) per share | \$ 0.13 | \$ (0.19) | \$ (1.22) |
| Weighted average shares outstanding | 6,099,453 | 5,565,149 | 5,237,425 |
| Diluted: | | | |
| Net income (loss) per share | \$ 0.12 | \$ (0.19) | \$ (1.22) |

| | | | |
|-------------------------------------|-----------|-----------|-----------|
| Weighted average shares outstanding | 6,825,196 | 5,565,149 | 5,237,425 |
|-------------------------------------|-----------|-----------|-----------|

See accompanying notes.

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Table of Contents**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY**

| | Common Shares | | Treasury Shares | | Common Share Warrants | | Accumulated Deficit | Foreign Currency Translation | Total |
|-------------------------------------|------------------|---------------|------------------|-----------------|-----------------------|-----------|---------------------|------------------------------|--------------|
| | Number of Shares | Stated Amount | Number of Shares | Cost | Number of Shares | Cost | | | |
| Balance at January 1, 2002 | 3,291,322 | \$ 50,372,239 | 3,300,000 | \$ (20,188,308) | | \$ | \$ (24,341,439) | \$ (87,687) | \$ 5,754,805 |
| Private placement of common shares | 1,922,514 | 3,473,792 | | | | | | | 3,473,792 |
| Issuance of common share warrants | | | | | 192,252 | 357,589 | | | 357,589 |
| Exercise of common share options | 50,000 | 7,500 | | | | | | | 7,500 |
| Stock compensation | | 14,772 | | | | | | | 14,772 |
| Comprehensive loss: | | | | | | | | | |
| Foreign currency translation | | | | | | | | 12,769 | 12,769 |
| Net loss | | | | | | | (6,390,610) | | (6,390,610) |
| Comprehensive loss | | | | | | | | | (6,377,841) |
| Balance at December 31, 2002 | 5,263,836 | \$ 53,868,303 | 3,300,000 | \$ (20,188,308) | 192,252 | 357,589 | (30,732,049) | (74,918) | \$ 3,230,617 |
| Private placement of common shares | 602,500 | 2,103,914 | | | | | | | 2,103,914 |
| Issuance of common share warrants | | | | | 25,125 | 135,424 | | | 135,424 |
| Exercise of common share options | 50,563 | 60,919 | | | | | | | 60,919 |
| Exercise of common share | 59,154 | 357,589 | | | (192,252) | (357,589) | | | |

| | | | | | | | | | | |
|---------------------|-----------|---------------|-----------|----------------|----------|------------|----------------|------------|--|---------------|
| Warrants | | | | | | | | | | |
| Stock | | | | | | | | | | |
| Compensation | 30,000 | 68,271 | | | | | | | | 68,271 |
| Comprehensive | | | | | | | | | | |
| Loss: | | | | | | | | | | |
| Foreign | | | | | | | | | | |
| Currency | | | | | | | | | | |
| Translation | | | | | | | | 50,307 | | 50,307 |
| Net loss | | | | | | | (1,048,621) | | | (1,048,621) |
| Comprehensive | | | | | | | | | | |
| Loss | | | | | | | | | | (998,314) |
| Balance at | | | | | | | | | | |
| December 31, | | | | | | | | | | |
| 2003 | 6,006,053 | 56,458,996 | 3,300,000 | (20,188,308) | 25,125 | 135,424 | (31,780,670) | (24,611) | | 4,600,831 |
| Private | | | | | | | | | | |
| Placement of | | | | | | | | | | |
| Common shares | 486,313 | 3,628,717 | | | | | | | | 3,628,717 |
| Issuance of | | | | | | | | | | |
| Common share | | | | | | | | | | |
| Warrants | | | | | 94,264 | 643,823 | | | | 643,823 |
| Exercise of | | | | | | | | | | |
| Common share | | | | | | | | | | |
| Options | 111,029 | 328,824 | | | | | | | | 328,824 |
| Exercise of | | | | | | | | | | |
| Common share | | | | | | | | | | |
| Warrants | 12,500 | 127,375 | | | (12,500) | (67,375) | | | | 60,000 |
| Stock | | | | | | | | | | |
| Compensation | | 40,198 | | | | | | | | 40,198 |
| Comprehensive | | | | | | | | | | |
| Income: | | | | | | | | | | |
| Foreign | | | | | | | | | | |
| Currency | | | | | | | | | | |
| Translation | | | | | | | | (1,949) | | (1,949) |
| Net income | | | | | | | 817,034 | | | 817,034 |
| Comprehensive | | | | | | | | | | |
| Income | | | | | | | | | | 815,085 |
| Balance at | | | | | | | | | | |
| December 31, | | | | | | | | | | |
| 2004 | 6,615,895 | \$ 60,584,110 | 3,300,000 | \$(20,188,308) | 106,889 | \$ 711,872 | \$(30,963,636) | \$(26,560) | | \$ 10,117,478 |

See accompanying notes

Table of Contents**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES****CONSOLIDATED STATEMENTS OF CASH FLOWS**

| | For the Year Ended December 31, | | |
|--|--|----------------|----------------|
| | 2004 | 2003 | 2002 |
| Operating Activities | | | |
| Net income (loss) | \$ 817,034 | \$ (1,048,621) | \$ (6,390,610) |
| Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities: | | | |
| Depreciation and amortization | 650,961 | 936,958 | 1,122,528 |
| Accretion of discount on investments | (27,420) | (14,456) | (61,571) |
| Stock compensation | 40,198 | 68,271 | 14,772 |
| Other | 18,203 | 6,330 | (23,838) |
| Changes in operating assets and liabilities: | | | |
| Accounts receivable | (1,211,706) | 95,242 | (429,573) |
| Prepaid expenses and other assets | (318,756) | (8,227) | 160,699 |
| Accounts payable and accrued expenses | 280,564 | (156,495) | (106,625) |
| Deferred revenue | (312,281) | (4,371) | 432,234 |
| Net cash used in operating activities | (63,203) | (125,369) | (5,281,984) |
| Investing Activities | | | |
| Decrease in restricted cash | 23,979 | 138,388 | 67,482 |
| Purchases of property and equipment | (1,054,189) | (183,520) | (1,273,687) |
| Maturities of short-term investments | 7,536,021 | 3,729,612 | 12,751,583 |
| Purchases of short-term investments | (10,661,709) | (5,626,095) | (10,575,124) |
| Other | | | 1,095 |
| Net cash (used in) provided by investing activities | (4,155,898) | (1,941,615) | 971,349 |
| Financing Activities | | | |
| Payments under capital lease obligation | (23,979) | (138,388) | (129,417) |
| Repayment, net, of notes receivable | 803 | 3,132 | 59,716 |
| Proceeds from issuance of shares, net of issuance costs | 4,375,665 | 2,239,338 | 3,831,381 |
| Proceeds from exercise of stock options and warrants | 388,824 | 60,919 | 7,500 |
| Net cash provided by financing activities | 4,741,313 | 2,165,001 | 3,769,180 |
| Effect of exchange rate on cash | (17,271) | 8,611 | (12,283) |
| Increase (decrease) in cash and cash equivalents | 504,941 | 106,628 | (553,738) |
| Cash and cash equivalents at beginning of year | 1,727,335 | 1,620,707 | 2,174,445 |

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| | | | |
|--|--------------|--------------|--------------|
| Cash and cash equivalents at end of year | \$ 2,232,276 | \$ 1,727,335 | \$ 1,620,707 |
| Cash paid during the year for interest | \$ 203 | \$ 6,701 | \$ 17,347 |
| Net cash paid during the year for income taxes | \$ 4,316 | \$ | \$ |
| Unpaid share issuance costs | \$ 103,125 | \$ | \$ |

See accompanying notes.

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DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

For the Years Ended December 31, 2004, 2003 and 2002

1. Accounting Policies

Description of Business

DATATRAK International, Inc. (DATATRAK or the Company) is an Application Service Provider (ASP) that provides electronic data capture (EDC) and other services, which assist companies in the clinical pharmaceutical, biotechnology, contract research organization (CRO) and medical device research industries, to accelerate the completion of clinical trials. The Company's wholly-owned subsidiary, DATATRAK GmbH, provides the Company with various customer support services and software development services. The Company's other wholly-owned subsidiary, DATATRAK Inc., is an inactive holding company with no employees that does not provide any services to the Company or its customers.

Principles of Consolidation

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

Revenue Recognition

DATATRAK's contracts provide a fixed price for each component or service to be delivered, and revenue is recognized as these components or services are delivered. Services provided by DATATRAK that are in addition to those provided for in its contracts are billed on a fee for service basis as services are completed. As services are performed over the life of the contract, revenue is recognized per the specific terms of each contract. Costs associated with contract revenue are recognized as incurred. Pass-through costs that are paid directly by the Company's clients, and for which the Company does not bear the risk of economic loss, are excluded from revenue. The termination of a standard contract will not result in a material adjustment to the revenue or costs previously recognized.

In some instances, the Company offers volume discounts to customers over multiple contracts. The Company estimates the volume discounts to be earned over the life the contracts to which the discount applies. As contracts progress, revenue is recorded using rates that reflect the anticipated volume discount to be achieved by the customer. The termination of a contract subject to a volume discount could result in a material adjustment to revenue previously recognized, in order to reflect the true economic value of the contract at the time of cancellation. For the year ended December 31, 2004, DATATRAK deferred \$69,000 of revenue as a result of its contracts subject to volume discounts. No revenue was deferred in 2003 or 2002 as a result of volume discounts.

Concentration of Credit Risk

The Company is subject to credit risk through accounts receivable and short-term investments. The Company generally does not require collateral and the majority of its accounts receivable are unsecured. Short-term investments are placed with high credit-quality financial institutions or in short-duration with high credit-quality debt securities. The Company limits the amount of credit exposure in any one institution or type of investment instrument.

Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Investments in cash equivalents are carried at cost which approximates market value.

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**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued
For the Years Ended December 31, 2004, 2003 and 2002**

Short-term Investments

Short-term investments are comprised of obligations of U.S. government agencies and corporate obligations with maturities of one year or less. These securities are stated at amortized cost, which approximates fair value. The Company has the positive intent and ability to hold the securities to maturity.

Property and Equipment

Property and equipment are stated at cost. Depreciable assets consist of office and computer equipment, software, and software development costs and leasehold improvements. Depreciation and amortization on office and computer equipment and software, and software development costs is computed using the straight-line method over estimated useful lives of 3 to 7 years. Leasehold improvements are amortized using the straight-line method over the lesser of the assets' estimated useful life or the lease term. Depreciation and amortization expense related to depreciable assets was \$651,000, \$937,000 and \$1,123,000 for 2004, 2003 and 2002, respectively.

Included in equipment at December 31 2003, is equipment under capital lease recorded at a cost of \$393,000. The lease obligation related to this equipment, was paid in full during 2004, and the Company retained possession of the equipment. Amortization expense related to this equipment was \$33,000 and \$131,000 in 2004 and 2003. Accumulated amortization related to this equipment was \$393,000 and \$360,000 at December 31, 2004 and 2003, respectively.

Impairment of Long-Lived Assets

The Company evaluates impairment of long-lived assets in accordance with Financial Accounting Standards Board (FASB) Statement of Financial Accounting Standards (SFAS) No. 144, Accounting for the Impairment of Long-Lived Assets. As such, the carrying values of long-lived assets are evaluated if circumstances indicate a possible impairment in value. If undiscounted cash flows over the remaining amortization period indicate that long-lived assets may not be recoverable, the carrying value will be reduced by the estimated shortfall of cash flows on a discounted basis.

Deferred Revenue

Deferred revenue represents cash advances received in excess of revenue earned on on-going contracts. Payment terms vary with each contract but may include an initial payment at the time the contract is executed, with future payments dependent upon the completion of certain contract phases or targeted milestones. In the event of contract cancellation, the Company is entitled to payment for all work performed through the point of cancellation.

Stock Based Compensation

The Company accounts for stock based compensation in accordance with Accounting Principles Board (APB) Opinion No. 25, Accounting for Stock Issued to Employees for stock options granted to employees and directors. The Company follows the alternative fair value accounting provided for under SFAS No. 123, Accounting for Stock-Based Compensation for stock options granted to non-employees. SFAS No. 123 requires use of option valuation models

that were not developed for use in valuing employee stock options. The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. FAS No. 148 requires disclosure of compensation expense under both APB No. 25 and SFAS No. 123. SFAS No. 123 requires that stock compensation

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DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued
For the Years Ended December 31, 2004, 2003 and 2002

be determined as if the Company has accounted for its stock options granted subsequent to December 31, 1994 under the fair value method of SFAS 123. The following assumptions were used to estimate the fair value for these options using the Black-Scholes option pricing model.

| | Year ended December 31 | | |
|---|-------------------------------|-------------|-------------|
| | 2004 | 2003 | 2002 |
| Weighted average risk free interest rate | 4.1% | 4.3% | 4.3% |
| Weighted average volatility of the expected market price of the common shares | 1.01 | 1.15 | 1.36 |
| Dividend yield | 0.0% | 0.0% | 0.0% |
| Weighted-average expected life of the option | 8 years | 7 years | 7 years |
| Weighted-average fair value per share of options granted | \$ 9.91 | \$ 3.86 | \$ 2.53 |

For purposes of pro forma disclosures, the estimated value of the options is amortized to expense over the options vesting period. The pro forma results are not necessarily indicative of what would have occurred had the Company adopted SFAS No. 123.

The following table sets forth stock based compensation and pro forma information for each period presented.

| | Year ended December 31, | | |
|---|--------------------------------|----------------|----------------|
| | 2004 | 2003 | 2002 |
| Net income (loss) recorded | \$ 817,000 | \$ (1,049,000) | \$ (6,391,000) |
| Plus: stock compensation expense recognized | 40,000 | 68,000 | 15,000 |
| Less: stock compensation expense that would have been recognized under SFAS No. 123 | 736,000 | 634,000 | 392,000 |
| Pro forma net income (loss) | \$ 121,000 | \$ (1,615,000) | \$ (6,768,000) |
| Pro forma basic income (loss) per share | \$ 0.02 | \$ (0.30) | \$ (1.36) |
| Pro forma diluted income (loss) per share | \$ 0.02 | \$ (0.30) | \$ (1.36) |

Use of Estimates

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

Financial Instruments

The carrying values of cash and cash equivalents, accounts and notes receivable, accounts payable and accrued expenses are reasonable estimates of fair value due to the short-term nature of these financial instruments. Investments are reported at amortized cost, which approximates fair value.

Advertising Costs

Advertising costs are expensed as incurred and are included in selling, general and administrative expenses. Advertising expenses were \$153,000, \$88,000 and \$282,000 for 2004, 2003 and 2002, respectively.

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**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued
For the Years Ended December 31, 2004, 2003 and 2002**

Software Development Costs

Development costs incurred in the research and development of new software products and enhancements to existing software products are expensed as incurred until technological feasibility has been established. After technological feasibility is established, any additional costs are capitalized in accordance with SFAS No. 86,

Accounting for the Costs of Computer Software to be Sold, Leased, or Otherwise Marketed. Such costs are amortized over the lesser of three years or the economic life of the related product. The Company performs an annual review of the recoverability of such capitalized software costs. At the time a determination is made that capitalized amounts are not recoverable based on the estimated cash flows to be generated from the applicable software, any remaining capitalized amounts are expensed.

Unamortized software and software development costs included in the Company's balance sheet was none and \$5,000 at December 31, 2004 and 2003, respectively. Amortization expense related to capitalized software costs was \$5,000, \$54,000 and \$54,000 in 2004, 2003 and 2002, respectively.

Research and development expenses included in selling, general and administrative expenses were \$1,142,000, \$850,000 and \$1,681,000 in 2004, 2003 and 2002, respectively.

Foreign Currency Translation

The assets and liabilities of the Company's foreign subsidiary are translated into U.S. dollars at current exchange rates. Revenue and expense accounts of these operations are translated at average rates prevailing during the period. These translation adjustments are accumulated in a separate component of shareholders' equity. Foreign currency transaction gains and losses are included in determining net loss when realized.

Recently Issued Accounting Standards

On December 16, 2004, the FASB issued SFAS No. 123(revised 2004), *Share-Based Payment*, which is a revision of SFAS No. 123. SFAS No. 123(R) supercedes APB No. 25, and amends SFAS No. 95, *Statement of Cash Flows*. Generally the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure is no longer an alternative.

SFAS 123(R) must be adopted no later than July 1 2005. Early adoption will be permitted in periods in which financial statements have not been issued. DATATRAK will adopt SFAS No. 123(R) on July 1, 2005. The Company will adopt SFAS No. 123 using the *modified prospective* method in which compensation cost is recognized beginning with the effective date based on the requirements of SFAS No. 123(R) for all share based payments granted after the effective date, and based on the requirements of SFAS No. 123 for all awards granted to employees prior to the effective date of SFAS No. 123(R) that remain unvested at the effective date.

As permitted by SFAS No. 123, the Company currently accounts for share based payments to employees using APB No. 25's intrinsic value method, and as such, generally recognizes no compensation cost for employee stock

options. Accordingly, the adoption of SFAS 123(R) s fair value method will have a significant impact on the Company s results of operations, although it will have no impact on its overall financial position. The adoption of SFAS 123(R) will increase the Company s operating expenses by approximately \$1,400,000 beginning in July 2005 through December 2008 for options that remain unvested as of July 1, 2005. The full impact of adoption of SFAS No. 123(R) cannot be predicted at this time because it will depend on levels of share based payments in the future.

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DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued
For the Years Ended December 31, 2004, 2003 and 2002

However, had the Company adopted SFAS No. 123(R) in prior periods, the impact of that standard would have approximated the impact of SFAS No. 123 as described in the disclosure of pro forma net income and earnings per share in Note 1 *Stock Based Compensation* to the Company's Consolidated Financial Statements.

Reclassification

Certain prior year amounts have been reclassified to conform to the current year reporting presentation.

2. Short-term Investments

The following is a summary of held-to-maturity securities:

| | December 31, 2004 | | December 31, 2003 | |
|---|--------------------------|---------------------------|--------------------------|----------------------------|
| | Cost | Amortized Cost | Cost | Amorti zed Cost |
| Obligations of U.S. government agencies | \$ 4,700,181 | \$ 4,708,482 | \$ 59,885 | \$ 59,964 |
| Corporate obligations | 978,400 | 978,475 | 2,490,597 | 2,497,864 |
| Less restricted portion | | | (23,979) | (23,979) |
| | \$ 5,678,581 | \$ 5,686,957 | \$ 2,526,503 | \$ 2,533,849 |

At December 31, 2003, the Company had a capital lease obligation with an unaffiliated third party in the amount of \$23,979. The terms of the capital lease agreement, required the Company to maintain a restricted cash balance equal to the outstanding balance payable on the lease. The capital lease obligation was paid in full during 2004.

3. Accounts Receivable

Accounts receivable consist of the following:

| | December 31, | |
|---------------------------------|---------------------|-------------|
| | 2004 | 2003 |
| Trade accounts receivable: | | |
| Billed | \$ 1,947,130 | \$ 788,241 |
| Unbilled | 56,445 | 5,681 |
| Total trade accounts receivable | 2,003,575 | 793,922 |
| Other | 36,873 | 34,820 |
| Allowance for doubtful accounts | (50,500) | (40,400) |

\$ 1,989,948 \$ 788,342

Movement of the allowance for doubtful accounts is as follows:

| | Year ended December 31, | | |
|--------------------------------------|--------------------------------|-------------|-------------|
| | 2004 | 2003 | 2002 |
| Balance at beginning of year | \$ 40,400 | \$ 40,400 | \$ 64,500 |
| Provision for uncollectible accounts | 10,100 | | 18,000 |
| Uncollectible accounts written off | | | (42,100) |
| Balance at end of year | \$ 50,500 | \$ 40,400 | \$ 40,400 |

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DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS - Continued
For the Years Ended December 31, 2004, 2003 and 2002

4. Accrued Expenses

Accrued expenses consist of the following:

| | December 31, | |
|----------------------------------|---------------------|-------------------|
| | 2004 | 2003 |
| Office rent and utilities | 144,056 | 157,197 |
| Payroll and other employee costs | 507,986 | 324,387 |
| Professional fees | 274,873 | 134,483 |
| Income and other taxes | 11,831 | 10,814 |
| Software license fees | 40,664 | |
| Other | 72,891 | 56,965 |
| | \$ 1,052,301 | \$ 683,846 |

5. Income Taxes

During 2004 and 2003, the Company provided for U.S. federal alternative minimum tax of \$9,000 and \$4,000, respectively. Due to its net losses and net loss carryforwards, the Company had no other federal, state or local income tax expense in 2004, 2003 and 2002. A reconciliation of income tax benefit at the U.S. federal statutory rate to the effective income tax rate is as follows:

| | Year ended December 31, | | |
|--|--------------------------------|-----------------|----------------|
| | 2004 | 2003 | 2002 |
| Income tax provision (benefit) at the United States statutory rate | \$ 281,000 | \$ (355,000) | \$ (2,173,000) |
| Non U.S. income tax (benefit) | 10,000 | (62,000) | (80,000) |
| Change in valuation allowance | (303,000) | 417,000 | 2,335,000 |
| Other | 21,000 | 4,000 | (82,000) |
| | \$ 9,000 | \$ 4,000 | \$ |

At December 31, 2004 the Company had a net operating loss carryforward of approximately \$20,071,000 for United States income tax purposes. The Company maintains a full valuation allowance against all net operating losses. An equity transaction completed on January 7, 2002 has limited the Company's net operating loss carryforwards, incurred prior to that date, to a maximum amount of \$967,000 per year, under Section 382 of the Internal Revenue Code. All of the Company's United States net operating loss carryforwards will begin expiring in the year 2018 and will be fully expired in the year 2022. The Company also has a net operating loss carryforward of approximately 10,332,000 Euro for German income tax purposes with no expiration date.

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DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
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The significant components of the Company's deferred tax assets (liabilities), stated in US dollars, are as follows:

| | December 31, | |
|---|---------------------|--------------|
| | 2004 | 2003 |
| Deferred tax assets (liabilities): | | |
| U.S. net operating loss carryforward | \$ 6,824,000 | \$ 7,113,000 |
| Non U.S. net operating loss carryforwards | 3,926,000 | 3,658,000 |
| Alternative minimum tax credit carryforward | 105,000 | 96,000 |
| Allowances and accruals | 69,000 | 158,000 |
| Depreciation and amortization | 56,000 | 9,000 |
| | 10,980,000 | 11,034,000 |
| Valuation allowance | (10,980,000) | (11,034,000) |
| Net deferred tax assets recorded | \$ | \$ |

6. Operating Leases

The Company leases certain office equipment and space. Rent expense relating to these operating leases was approximately \$603,000, \$583,000 and \$478,000 in 2004, 2003 and 2002, respectively. Future minimum lease payments for the Company under noncancelable operating leases as of December 31, 2004 are as follows:

| Year ending December 31, | Amount |
|---------------------------------|---------------|
| 2005 | \$ 592,000 |
| 2006 | 596,000 |
| 2007 | 551,000 |
| 2008 | 561,000 |
| 2009 | 443,000 |
| Subsequent to 2009 | 971,000 |
| | \$ 3,714,000 |

7. Shareholders' Equity

In January 2002, the Company completed a private placement of its common shares with certain outside investors. The Company sold 1,922,514 of its common shares at a price of \$2.25 per share. Net of expenses, the Company raised \$3,831,000 in cash. In conjunction with this private placement, DATATRAK issued 192,252 warrants to purchase common shares at a price of \$2.25 per share. The warrants, which contained a provision for a cashless exercise, were

fully vested as of the grant date. A non-cash charge of \$371,590 to shareholders' equity was recorded as a result of stock options and warrants that were granted and vested due to the Company's January 2002 private placement of common shares. During June 2003, the holders exercised these warrants and converted them into 59,154 common shares in a non-cash transaction.

Effective April 21, 2003, the Company entered into an agreement for consulting services related to its investor relations program. As compensation for these services, the Company issued 30,000 restricted common shares to an outside consultant. During the year ended December 31, 2003, a non-cash charge of \$42,000 was recorded as compensation expense for these common shares.

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In addition, the same investor relations consultant was granted an option to purchase 25,000 common shares on May 27, 2003. The exercise price of the options is \$2.64 per share, the market price of the common shares on the date of grant. DATATRAK has recorded \$22,000 and \$13,000 of compensation expense related to these options during the years ended December 31, 2004 and 2003, respectively. The option will become exercisable in equal amounts over a three-year period and expires on the tenth anniversary of the date of grant. The option was granted under the Company's Amended and Restated 1996 Key Employees and Consultants Stock Option Plan (the "1996 Plan").

On August 8, 2003, the Company completed another private placement of its common shares with certain outside investors. The Company sold 602,500 of its common shares at a price of \$4.00 per share. Net of expenses, the Company raised \$2,239,000 in cash. In conjunction with this private placement, DATATRAK issued 25,125 warrants to purchase common shares at a price of \$4.80 per share. The warrants, which were valued at \$135,424, are fully vested as of the grant date and will expire five years from the date of grant. During 2004, the holders of 12,500 of these common share warrants surrendered the warrants along with the exercise price in exchange for 12,500 common shares.

On December 28, 2004, the Company completed another private placement of common shares with outside investors. The Company sold 486,313 of its common shares at a price of \$9.50 per share. Net of expenses, the Company raised \$4,273,000 in cash. In conjunction with this private placement, DATATRAK issued 94,264 warrants to purchase common shares at a price of \$14.40 per share. The warrants, which were valued at \$643,823, are fully vested as of the grant date and will expire three years from the date of grant. All of the warrants were outstanding as of December 31, 2004.

Reserved Shares

At December 31, 2004, the Company had reserved 1,621,631 common shares for the exercise of common share options and warrants.

Serial Preferred Shares

At December 31, 2004 and 2003, the Company had 1,000,000 Serial Preferred Shares, without par value, authorized, with none outstanding.

Treasury Shares

At December 31, 2004 and 2003, the Company held 3,300,000 of its common shares in treasury at a cost of \$20,188,308.

8. Share Option Plans

The Company has five share option plans. At December 31, 2004, the Company had reserved 2,032,375 common shares for the exercise of common share options. The Company has granted 1,843,360 options to purchase common shares to employees, directors and others of which 517,633 have been previously exercised. There are 188,775 options

to purchase common shares available for future grants. The weighted average contractual life of all options outstanding was 6.3 years as of December 31, 2004. The range of exercise prices for all options outstanding at December 31, 2004 was \$2.00 to \$11.34.

The Amended and Restated 1992 Share Incentive Plan (the 1992 Plan) was approved by the Company's shareholders for the purpose of granting common share options to employees and consultants of the Company and its

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affiliates. Certain options granted under the 1992 Plan were granted at exercise prices of less than the fair market value of a common share on the date of grant. All compensation expense related to these options has been previously recognized. All other options to purchase common shares awarded under the 1992 Plan were granted at exercise prices that represented the fair market value of a common share on the date of grant. All options granted under the 1992 Plan expire ten years after the grant date. At December 31, 2004 there were 35,000 options outstanding under the 1992 Plan with an exercise price of \$4.15, all of which were 100% vested. These options will expire in 2005, and there will be no future grants of options under the 1992 Plan.

The Amended and Restated 1994 Directors' Share Option Plan (the 1994 Director Plan) was established by the Company to provide common share options to directors of the Company for their participation in Board of Directors meetings. All options awarded under the plan have an exercise price per share that was equal to the fair market value of a common share on the date of grant. All options granted under the 1994 Director Plan expire ten years after the grant date. At December 31, 2004 there were 4,001 options outstanding under the 1994 Director Plan with exercise prices ranging from \$4.15 to \$9.60, all of which were 100% vested. These options had a weighted average contractual life of 0.8 years and a weighted average exercise price of \$6.68. There will be no future grants of options under the 1994 Director Plan.

The Amended and Restated 1996 Outside Directors' Stock Option Plan, as amended (the 1996 Director Plan) was established by the Company to provide common share options as compensation to directors of the Company. Certain options, as approved by the Company's shareholders, were granted under the 1996 Director Plan at exercise prices below the market value of a common share on the date of approval. All compensation expense related to these common share options has been previously recognized by the Company. All other options granted under the 1996 Director Plan have been granted at exercise prices that represented the fair market value of a common share on the date of grant. At December 31, 2004 there were 55,000 options outstanding under the 1996 Director Plan with exercise prices ranging from \$4.19 to \$9.60, all of which were 100% vested. These options had a weighted average contractual life of 3.2 years and a weighted average exercise price of \$4.98. There will be no future grants of options under the 1996 Director Plan.

The 1996 Plan provides for the granting of a maximum of 1,057,667 options to purchase common shares to key employees and consultants of the Company and its affiliates. During 2000, 77,354 common share options were granted at exercise prices of less than the fair market value of a common share on the date of grant. The Company recognized compensation expense related to these common share options of \$14,000 and \$15,000 in 2003 and 2002, respectively. All other options granted under the 1996 Plan have been granted at exercise prices that represented the fair market value of a common share on the date of grant. In addition, the Company has recorded compensation expense of \$40,000 and \$12,000 in 2004 and 2003, respectively, related to options granted to non-employees. Vesting of options awarded under the 1996 Plan is determined by the Board of Directors' Compensation Committee, and all options granted under the 1996 Plan expire ten years after the grant date. At December 31, 2004 there were 831,466 options outstanding under the 1996 Plan with exercise prices ranging from \$2.00 to \$11.34, of which 517,537 were 100% vested. These options had a weighted average contractual life of 6.6 years and a weighted average exercise price of \$5.35.

The Amended and Restated Outside Director Stock Option Plan (the Director Plan) provides for the granting of a maximum of 550,000 options to purchase common shares to outside directors of the Company. Certain options approved by Company s Board of Directors and its shareholders have been granted at exercise prices below the market value of a common share, on the grant date in 2000. All compensation expense related to these common share options has been previously recognized by the Company. All other options granted under the Director Plan have been granted at exercise prices that represented the fair market value of a common share on the date of grant. Options fully vest one year following the grant date. All options granted under the Director Plan expire ten years after the grant date. At December 31, 2004 there were 400,500 options outstanding under the Director Plan with

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exercise prices ranging from \$2.00 to \$11.34, of which 360,000 were 100% vested. These options had a weighted average contractual life of 6.8 years and a weighted average exercise price of \$4.21.

The Company's share option activity and related information is summarized below:

| | Year ended December 31, | | | | | |
|------------------------------------|-------------------------|--|-----------|--|-----------|--|
| | 2004 | | 2003 | | 2002 | |
| | Options | Weighted Average Exercise Price | Options | Weighted Average Exercise Price | Options | Weighted Average Exercise Price |
| Outstanding at beginning of Period | 1,313,295 | \$ 4.10 | 1,026,782 | \$ 3.85 | 1,095,083 | \$ 3.73 |
| Granted | 146,750 | 11.12 | 382,131 | 4.28 | 82,270 | 2.78 |
| Exercised | (111,029) | 2.96 | (50,563) | 1.20 | (50,000) | 0.15 |
| Cancelled | (23,049) | 4.67 | (45,055) | 3.18 | (100,571) | 3.56 |
| Outstanding at end of period | 1,325,967 | \$ 4.96 | 1,313,295 | \$ 4.10 | 1,026,782 | \$ 3.85 |
| Exercisable at end of period | 971,538 | \$ 4.05 | 917,924 | \$ 4.01 | 696,698 | \$ 4.04 |

9. Retirement Savings Plan

The Company sponsors The DATATRAK International, Inc. Retirement Savings Plan (the Plan) as defined by Section 401(k) of the Internal Revenue Code of 1986, as amended. The Plan covers substantially all United States employees who elect to participate. Participants may contribute up to 20% of their annual compensation into a variety of mutual fund options. Matching and profit sharing contributions by the Company are discretionary. The Company did not make any matching or profit sharing contributions in 2004, 2003 or 2002.

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10. Net Income (Loss) Per Share

The following table sets forth the computation of basic and diluted earnings per share.

| | Year Ended December 31, | | |
|---|--------------------------------|----------------|----------------|
| | 2004 | 2003 | 2002 |
| Net income (loss) used in the calculation of basic and diluted loss per share | \$ 817,034 | \$ (1,048,621) | \$ (6,390,610) |
| Denominator for basic net income (loss) per share weighted average common shares outstanding | 6,099,453 | 5,565,149 | 5,237,425 |
| Effect of dilutive common share options and warrants | 725,743 | | |
| Denominator for diluted net income (loss) per share | 6,825,196 | 5,565,149 | 5,237,425 |
| Basic net income (loss) per share | \$ 0.13 | \$ (0.19) | \$ (1.22) |
| Diluted net income (loss) per share | \$ 0.12 | \$ (0.19) | \$ (1.22) |
| Weighted average common share options and warrants excluded from the computation of diluted net income (loss) per share because they would have an antidilutive effect on net income (loss) per share | 42,286 | 1,230,927 | 1,255,590 |

11. Segment Information

The Company operates in one business segment: the DATATRAK EDC Business.

*Enterprise-Wide Disclosures**Geographic Information*

| Year ended December 31, | United States | Germany | Total |
|--------------------------------|----------------------|----------------|---------------|
| Revenue: | | | |
| 2004 | \$ 11,305,112 | \$ | \$ 11,305,112 |
| 2003 | \$ 7,052,158 | \$ | \$ 7,052,158 |
| 2002 | 4,598,769 | 122,143 | 4,720,912 |
| Net income (loss): | | | |
| 2004 | 4,347,926 | (3,530,892) | 817,034 |

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| | | | |
|--|-------------|-------------|-------------|
| 2003 | 1,523,476 | (2,572,097) | (1,048,621) |
| 2002 | (3,299,207) | (3,091,403) | (6,390,610) |
| Long-lived assets, net at December 31, | | | |
| 2004 | 1,283,793 | 138,971 | 1,422,764 |
| 2003 | 886,601 | 132,138 | 1,018,739 |

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DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
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Major Customers

The following sets forth the percentage of revenue generated by customers who accounted for more than 10% of the Company's revenue during each of the periods presented:

| Customer | Year ended December 31, | | |
|---------------------------|-------------------------|------|------|
| | 2004 | 2003 | 2002 |
| Aventis Pharmaceuticals | 12% | 22% | 29% |
| Control Delivery Systems | * | 11% | 20% |
| Daiichi Pharmaceutical | * | * | 10% |
| Otsuka Research Institute | 45% | 20% | * |

* Less than 10% of revenue.

12. Restricted Cash

DATATRAK GmbH is required to provide a bank guarantee to the lessor of its office space equal to three months rent. The terms of the bank guarantee require DATATRAK GmbH to maintain a restricted cash balance of 59,000 Euros with the bank. The U.S. dollar equivalent of this amount was \$80,611 at December 31, 2004.

13. Special Items

During the third quarter of 2002, the Company recorded a special charge of \$238,000. This charge was for severance and other costs associated with DATATRAK's staff reduction of 20 employees, whose positions were eliminated during the third quarter of 2002. As of December 31, 2003, all of these costs had been paid.

On September 23, 2002 the Company announced the signing of a definitive agreement to purchase Oriam, SA, a French technology firm with offices in Paris, France and Boston, Massachusetts. Expenses totaling \$126,000 associated with this purchase agreement were recorded as special charges during September 2002. In January 2003, the Company announced that the proposed acquisition would not be completed.

14. Commitments

The Company has entered into an alliance with SAS Institute Inc. ("SAS") pursuant to which they are making a joint offering to customers to gather and analyze clinical trial data. During the initial two-year term of the alliance, the Company is obligated to make an aggregate of \$650,000 in fixed payments to SAS, for among other things, access to the SAS® Drug Development software. The first payment of \$250,000 was made in December 2004. A second payment of, \$250,000 will be made by the end of February 2005 and the remaining \$150,000 will be paid by the end of January 2006. The Company is also entitled to provide similar use of the SAS software to its customers during a third option year upon the payment of a \$200,000 fixed fee. The Company will charge fees to its customers that utilize the SAS software.

The total payments to SAS totaling \$650,000 will be expensed on a straight line basis over the two year life of the alliance agreement. Any incremental data item fees associated with the alliance will be expensed as incurred.

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15. Quarterly Data (Unaudited)

Selected quarterly data is as follows (in thousands):

| | Year Ended December 31, 2004 | | | |
|-------------------------------------|-------------------------------------|---------------------------|--------------------------|---------------------------|
| | First Quarter | Second Quarter | Third Quarter | Fourth Quarter |
| Revenue | \$ 2,288 | \$ 2,630 | \$ 2,974 | \$ 3,413 |
| Gross profit | 1,755 | 2,025 | 2,292 | 2,599 |
| Income (loss) from operations | (99) | 96 | 386 | 408 |
| Net income (loss) | (95) | 89 | 398 | 425 |
| Basic net income (loss) per share | (0.02) | 0.01 | 0.07 | 0.07 |
| Diluted net income (loss) per share | (0.02) | 0.01 | 0.06 | 0.06 |

| | Year Ended December 31, 2003 | | | |
|--------------------------------------|-------------------------------------|---------------------------|--------------------------|---------------------------|
| | First Quarter | Second Quarter | Third Quarter | Fourth Quarter |
| Revenue | \$ 1,457 | \$ 1,735 | \$ 1,895 | \$ 1,965 |
| Gross profit | 1,103 | 1,389 | 1,484 | 1,454 |
| Loss from operations | (498) | (191) | (73) | (295) |
| Net loss | (495) | (188) | (68) | (298) |
| Basic and diluted net loss per share | (0.09) | (0.04) | (0.01) | (0.05) |

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| Exhibit No. | Description | Page |
|--------------------|--|-------------|
| 3.1 | Sixth Amended and Restated Articles of Incorporation | (1) |
| 3.2 | Third Amended and Restated Code of Regulations | (2) |
| 3.3 | Amendment to the Third Amended and Restated Code of Regulations | (2) |
| 3.4 | Amendment to the Third Amended and Restated Code of Regulations | (1) |
| 4.1 | Specimen Certificate of the Company's Common Shares, without par value | |
| 4.2 | Form of Warrant Agreement, dated August 8, 2003 | (7) |
| 4.3 | Form of Warrant Agreement, dated December 28, 2004 | |
| 10.1 | Amended and Restated 1994 Directors' Share Option Plan* | (4) |
| 10.2 | Amendment to the Amended and Restated 1994 Directors' Share Option Plan* | (2) |
| 10.3 | Amended and Restated 1996 Outside Directors' Stock Option Plan* | (4) |
| 10.4 | Amendment No. 1 to the Amended and Restated 1996 Outside Directors' Stock Option Plan* | (2) |
| 10.5 | Amendment No. 2 to the Amended and Restated 1996 Outside Directors' Stock Option Plan* | (2) |
| 10.6 | Amendment to the Amended and Restated 1996 Outside Directors' Stock Option Plan* | (2) |
| 10.7 | Amended and Restated 1992 Share Incentive Plan* | (4) |
| 10.8 | Amendment to the Amended and Restated 1992 Share Incentive Plan* | (2) |
| 10.9 | Amended and Restated 1996 Key Employees' and Consultants Stock Option Plan* | (4) |
| 10.10 | Amendment No. 1 to the Amended and Restated 1996 Key Employees' and Consultants Stock Option Plan* | (2) |
| 10.11 | Amendment No. 2 to the Amended and Restated 1996 Key Employees' and Consultants Stock Option Plan* | (2) |
| 10.12 | Amendment No. 3 to the Amended and Restated 1996 Key Employees' and Consultants Stock Option Plan* | (2) |
| 10.13 | Amendment to the Amended and Restated 1996 Key Employees' and Consultants Stock Option Plan* | (2) |
| 10.14 | Amended and Restated Outside Director Stock Option Plan* | (8) |

10.15 Form of Indemnification Agreement*

(3)

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| Exhibit No. | Description | Page |
|--------------------|---|-------------|
| 10.16 | Employment Agreement between the Company and Jeffrey A. Green, dated February 5, 2001* | (5) |
| 10.17 | Employment Agreement between the Company and Terry C. Black, dated February 5, 2001* | (5) |
| 10.18 | Employment Agreement between the Company and Marc J. Shlaes dated March 5, 2003* | (2) |
| 10.19 | Managing Director Employment Agreement between the Company and Wolfgang Summa, dated December 29, 2000* | (5) |
| 10.21 | DATATRAK International, Inc. Retirement Savings Plan* | (6) |
| 14.1 | Code of Business Conduct and Ethics | (7) |
| 14.2 | Financial Code of Ethics | (7) |
| 21.1 | Subsidiaries of the Company | |
| 23.1 | Consent of Ernst & Young LLP | |
| 31.1 | Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer | |
| 31.2 | Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer | |
| 32.1 | Section 1350 Certification of Chief Executive Officer | |
| 32.2 | Section 1350 Certification of Chief Financial Officer | |

* Management compensatory plan or arrangement.

- (1) Incorporated herein by reference to the Company's Form 10-Q for the quarter ended June 30, 2003 (File No. 000-20699).
- (2) Incorporated herein by reference to the Company's Form 10-K for the year ended December 31, 2002 (File No. 000-20699).
- (3) Incorporated herein by reference to the Company's Form S-1 Registration Statement filed on March 8, 1996, as amended by Amendment No. 1 filed on May 10, 1996 and as amended by Amendment No. 2 filed on June 10, 1996 (File No. 333-2140).
- (4) Incorporated herein by reference to the Company's Form S-8 Registration Statement filed on November 13, 1996 (File No. 333-16061).
- (5) Incorporated herein by reference to the Company's Form 10-K for the year ended December 31, 2000 (File No. 000-20699).

- (6) Incorporated herein by reference to the Company's Form S-8 Registration Statement filed on April 30, 1997 (File No. 333-26251).

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- (7) Incorporated herein by reference to the Company's Form 10-K for the year ended December 31, 2003 (File No. 000-20699).
- (8) Incorporated herein by reference to the Company's Form 10-Q for the quarter ended June 30, 2004 (File No. 000-20699).

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