

DATATRAK INTERNATIONAL INC

Form 10-K

March 27, 2003

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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  
 For the fiscal year ended December 31, 2002

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
 For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 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

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 February 28, 2003, the registrant had 5,263,836 Common Shares, without par value, issued and outstanding. As of June 30, 2002, the aggregate market value of the 4,848,138 shares then outstanding, which together constituted all of the voting shares of the registrant, held by non-affiliates was \$13,332,380 (based upon the closing price of \$2.75 per Common Share on the Nasdaq Stock Market, Inc. on June 30, 2002).

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For purposes of this calculation, the registrant deems the 415,698 Common Shares held by all of its Directors and executive officers to be the Common Shares held by affiliates.

### **DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive Proxy Statement to be used in connection with its Annual Meeting of Shareholders to be held on June 3, 2003 are incorporated by reference in Part III of this Form 10-K.

Except as otherwise stated, the information contained in this Form 10-K is as of December 31, 2002.

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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.

We were founded in 1991 as a site management organization, and through our Clinical Business, which we sold in April 1999, provided clinical research services to various clinical trial sponsors. We currently operate as an ASP 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 for \$610,000. 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.

In January 2002, we received approximately \$3,840,000 in net proceeds from a private placement of 1,922,514 of our common shares at a purchase price of \$2.25 per share. The terms of this financing included the issuance of five-year warrants to purchase a total of 192,252 common shares at \$2.25 per share to Stonegate Securities, Inc., our placement agent for the private placement. The proceeds of the private placement have been used to expand our worldwide marketing and sales efforts, to continue to enhance our DATATRAK EDC® software and for other general working capital purposes.

In September 2002, we signed a definitive agreement to purchase Oriam, SA, a French technology firm. Closing of the proposed transaction was contingent upon receiving appropriate financing. In January 2003, we withdrew from the definitive purchase agreement, since appropriate financing was not received. During 2002 we recorded special items charges of \$120,000 related to the proposed acquisition. There was no cost to us associated with the withdrawal from this purchase agreement.

Also during the second half of 2002, we took steps to streamline our cost structure primarily through staff reductions and payroll cost savings. We believe these actions will reduce our annual expenses by approximately \$2,380,000. These steps will allow us to lower our break-even point, and achieve profitability more quickly than previously anticipated.

**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 clinical trial sponsors adequately test new drugs and medical devices prior to marketing these drugs and devices. As a result of these regulatory requirements, we estimate that companies in this industry spend approximately \$41.0 billion annually on clinical research, including approximately \$12.0 billion for the collection, analysis and management of clinical trial data.

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

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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. Clinical trial sponsors 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, research associates visit research sites to review clinical trial data, which is manually entered on the paper case report form, for accuracy and integrity. During these 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 research sponsor. Several weeks, or even months, of data may be reviewed during each monitoring visit. At the completion of a monitoring visit, the 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.

We believe that automating data entry and review procedures can save time in the drug development process. Our belief is supported by metrics presented by an international pharmaceutical manufacturer, in 1998. The use of DATATRAK EDC® in a clinical trial was compared with the traditional, or paper, method of data collection and review in a clinical trial of similar size and complexity. The study showed that DATATRAK EDC® reduced the overall length of the clinical trial by 30%. Further, the time required to achieve a final, locked database was reduced by 40%, through the use of DATATRAK EDC®. Finally, due to the improved quality of the clinical trial data obtained through the use of DATATRAK EDC® the study showed an 86% reduction in questions concerning that clinical trial data. We can provide any customer with the DATATRAK® process as a competitive advantage by accelerating the review and processing of clinical trial data.

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. The DATATRAK EDC® software and its earlier versions have supported many international clinical studies involving thousands of clinical research sites and tens of thousands of patients in 39 countries. Our product suite has been utilized in the clinical development of 13 separate drugs that have received regulatory approval from either the FDA or counterpart regulatory bodies in Europe.

DATATRAK EDC® is a technology platform that consists of Windows compatible software and hardware designed to assist clinical trial sponsors in starting and finishing their clinical trials on a more timely basis. Our combination of software and hardware expedites the data collection and reporting process during a clinical trial. 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. We are continually enhancing and testing the DATATRAK EDC® software and developing the DATATRAK® process. Research and development expenses were \$1,680,000, \$1,660,000 and \$890,000 in 2002, 2001 and 2000, respectively.

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 or dial-up connection. 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 or dial-up connection. After the data is reviewed and cleansed of all entry errors, DATATRAK EDC®'s report 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

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database. Under this model, research data is collected more quickly and with greater accuracy than with physical review of paper reports.

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.

**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. Since the market for EDC in general and for our services specifically, has been an emerging one, the effectiveness of our marketing efforts has been limited. However, we have selectively participated in scientific and medical meetings to promote our services and have occasionally used direct mail and journal advertisements to build awareness of our capabilities.

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. Also, DATATRAK EDC® can be used via the Internet and can be used in multiple languages. Furthermore, a clinical trial sponsor has published statistics indicating that DATATRAK 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.

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 and other factors. 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 revenue generated from customers who accounted for more than 10% of the Company's revenue and percentage of revenue generated by all other customers during 2002, 2001 and 2000.

Customer	Year ended December 31,		
	2002	2001	2000
Aventis Pharmaceuticals	29%	22%	27%
Control Delivery Systems	20%	23%	*
CV Therapeutics	*	21%	*
Quintiles	*	11%	52%
Daiichi Pharmaceutical	10%	*	0%
All other customers	39%	21%	10%

\* Less than 10% of revenue.

**Contracting and Backlog**

Our 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



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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 contract will not result in a material adjustment to the revenue or costs we have previously recognized.

We are also a seller and licensor of software. Generally, we recognize revenue upon delivery of sold software. Licensing revenue is recognized ratably over the life of the license. To date we have not recognized any revenue from software sales.

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 have passed the verbal stage, but have not yet been signed. At December 31, 2002, our backlog was \$12,620,000 compared to backlog of \$11,920,000 at December 31, 2001. The December 31, 2001 backlog included a \$2,410,000 contract that was placed on hold by the customer. At December 31, 2002 this contract had been removed from backlog. We expect to convert \$5,110,000 of our December 31, 2002 backlog into revenue during 2003. Subsequent to year end, we have added additional contracts to backlog that we expect will generate approximately \$850,000 of additional revenue. However, our contracts can be cancelled or delayed at anytime, therefore our backlog, at any point in time, is not an accurate predictor of future levels of revenue.

## **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. We compete in this 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. We believe that we may be able to enhance our competitive strength through the formation of strategic alliances with established industry organizations. We have received expressions of interest from various parties in establishing such relationships.

Our major competitors include software vendors specializing in EDC, clinical trial data service companies, large pharmaceutical companies currently developing their own in-house technology and the traditional paper-based method of collecting clinical trial data. 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. 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 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

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believe DATATRAK EDC® complies with these guidelines and rules. Because the FDA's guidance and rules are still developing, DATATRAK EDC® may not remain consistent with the FDA's requirements. Any release of additional FDA guidance that is significantly inconsistent with the design of DATATRAK EDC® could cause us to incur significant costs in order to change our software. We intend to continue to monitor the FDA's guidance to ensure compliance.

### **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. We maintain a \$5.0 million errors and omissions professional liability insurance policy to cover claims that may be brought against us. This coverage may not be adequate, or continue to be available in the future.

### **Patents and Trademarks**

We hold registered service marks, including the DATATRAK EDC® software, incorporating the DATATRAK® process and trademarks. The DATATRAK EDC® software is the foundation of the DATATRAK® process. Intellectual property rights are significant to our continued operation and development.

### **Employees**

As of February 28, 2003, we had approximately 55 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.

## **ITEM 2. PROPERTIES**

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 5,000 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**

None.

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No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year ended December 31, 2002.

**ITEM 4A. EXECUTIVE OFFICERS OF THE COMPANY\***

The name, age and positions of each of the Company's executive officers are as follows:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Dr. Jeffrey A. Green	47	President, Chief Executive Officer and Director
Terry C. Black	45	Vice President of Finance, Chief Financial Officer, Treasurer and Assistant Secretary
Marc J. Shlaes	48	Vice President of Research and Development
Dr. Wolfgang Summa	38	Vice President of Global Operations

\* Included pursuant to Instruction 3 to Item 401(b) of Regulation S-K.

Jeffrey A. Green, Pharm.D., FCP, is our founder and has served as our President, Chief Executive Officer and a Director since March 1992. From 1984 to 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. In addition, Dr. Green was an established investigator in clinical cardiology and PET scanning, 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. He was the recipient of the McKeen Cattell Distinguished Achievement Award from the American College of Clinical Pharmacology in 1988. Dr. Green is a graduate of Purdue University (B.S.) and the University of Texas (Pharm.D.).

Terry C. Black, MBA, CPA, 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, 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. From October 1999 through December 2000, Mr. Shlaes served as our Vice President and Managing Director of North America. Prior to his appointment as Vice President and Managing Director of North America, Mr. Shlaes served 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, including as an employee of International Business Machines from 1982 to 1996.

Wolfgang Summa, PhD., MSc., has served as our Vice President of Global Operations since December 2000. Dr. Summa is responsible for our operational strategy including the delivery of DATATRAK EDC® to customers as well as the management of our clinical trials. From October 1999 through December 2000, Dr. Summa served as our Vice President and Managing Director of Europe. From January 1998 to October 1999, Dr. Summa served as our Manager of European Operations. Prior to joining us, Dr. Summa served in various research positions within the electronic data capture industry for PadCom Clinical Research and Electronic Data Systems.

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

On February 12, 2003 we received a Nasdaq Staff Determination indicating that we failed to comply with the minimum \$10 million stockholders' equity requirement for continued listing as set forth in Nasdaq Marketplace Rule 4450(a)(3), and that our common shares were subject to delisting from the Nasdaq National Market. In response to these developments, we voluntarily elected to file an application with Nasdaq to transfer the listing of our common shares from the Nasdaq National Market to the Nasdaq SmallCap Market. Our transfer application was approved by Nasdaq and our common shares began trading on the Nasdaq SmallCap Market on March 26, 2003.

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 fiscal years ended December 31, 2002 and 2001, the high and low sale prices per common share, as reported by Nasdaq. These prices do not include retail markups, markdowns or commissions.

	<b>High</b>	<b>Low</b>
2002		
First Quarter	\$4.46	\$2.30
Second Quarter	\$3.70	\$2.39
Third Quarter	\$3.00	\$1.50
Fourth Quarter	\$2.00	\$0.75
2001		
First Quarter	\$4.06	\$2.56
Second Quarter	\$2.75	\$1.50
Third Quarter	\$3.40	\$1.21
Fourth Quarter	\$4.99	\$2.30

On February 28, 2003, the last sale price of our common shares as reported by Nasdaq was \$0.98 per share. As of February 28, 2003, we had 76 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,				
	2002	2001	2000	1999	1998
(In thousands, except per share data)					
<b>Statement of Operations Data:</b>					
Revenue	\$ 4,721	\$ 2,246	\$ 1,994	\$ 5,811	\$ 13,226
Direct costs	1,804	1,780	1,597	3,763	10,511
Gross profit	2,917	466	397	2,048	2,715
Selling, general and administrative expenses	7,893	7,210	5,726	5,871	8,969
Impairment charge					6,056
Special items	364				1,998
Depreciation and amortization	1,122	949	867	800	1,155
Loss from operations	(6,462)	(7,693)	(6,196)	(4,623)	(15,463)
Other income, net	71	339	912	14,727	1,467
(Loss) Income before income taxes	(6,391)	(7,354)	(5,284)	10,104	(13,996)
Income tax expense				384	80
Net (loss) income	\$ (6,391)	\$ (7,354)	\$ (5,284)	\$ 9,720	\$ (14,076)
Net (loss) income per share: basic	\$ (1.22)	\$ (2.23)	\$ (1.61)	\$ 1.87	\$ (2.19)
Shares used in the computation of basic net (loss) income per share	5,237	3,291	3,290	5,209	6,422
Net (loss) income per share: diluted	\$ (1.22)	\$ (2.23)	\$ (1.61)	\$ 1.84	\$ (2.19)
Shares used in the computation of diluted net (loss) income per share	5,237	3,291	3,290	5,293	6,422

	December 31,				
	2002	2001	2000	1999	1998
(In thousands, except per share data)					
<b>Balance Sheet Data:</b>					
Cash, cash equivalents and short-term investments	\$ 2,468	\$ 5,204	\$ 12,040	\$ 17,536	\$ 26,693
Working capital	1,466	4,291	11,645	16,983	24,489
Total assets	5,306	7,634	14,486	19,483	33,540
Long-term liabilities	24	162			
Accumulated deficit	(30,732)	(24,341)	(16,987)	(11,703)	(21,423)
Total shareholders' equity	3,231	5,755	13,104	18,306	28,238
Book value per common share	\$ 0.61	\$ 1.75	\$ 3.98	\$ 5.56	\$ 4.40
Cash dividends declared					

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The selected financial data presented above includes the operating results of our Clinical Business for all periods presented prior to April 20, 1999. Prior to April 20, 1999, the date we sold our Clinical Business, substantially all of our revenue and operating results were derived from the Clinical Business.

### **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.

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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.

Approximately 47% of our assets, or approximately \$2,470,000, is held in cash, cash equivalents and short-term investments. Since commencing EDC operations in 1997, we have experienced some growth in revenue but continue to record significant losses and negative cash flow from operations. 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 intranet 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.

Our 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 contract will not result in a material adjustment to the revenue or costs we have previously recognized.

At December 31, 2002, our backlog was \$12,620,000 compared to backlog of \$11,920,000 at December 31, 2001. The December 31, 2001 backlog included a \$2,410,000 contract that was placed on hold by the customer. At December 31, 2002 this contract has been removed from backlog. We expect to convert \$5,110,000 of our December 31, 2002 backlog into revenue during 2003. Subsequent to year end, we have added additional contracts to backlog that we expect will generate approximately \$850,000 of additional revenue. However, our contracts can be cancelled or delayed at anytime, therefore our backlog, at any point in time, is not an accurate predictor of future levels of revenue. In the future, we may also record revenue related to the sales and licensing of software.

## **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 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 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 contract will not result in a material adjustment to the revenue or costs previously recognized.

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### *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 Statement of Financial Accounting Standards 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. 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 Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB 25 ). Under APB 25, we recognize compensation expense for all stock options granted at less than the fair market value of our common shares on the date of grant. The alternative fair value accounting provided for under Financial Accounting Standards Board Statement No. 123, *Accounting for Stock-Based Compensation* ( Statement No. 123 ) requires use of option valuation models that were not developed for use in valuing employee stock options.

### **Recently Issued Accounting Standards**

In June 2002, the Financial Accounting Standards Board issued Statement No. 146, *Accounting for Costs Associated with Exit or Disposal Activities* ( Statement No. 146 ), which is effective for exit or disposal activities that are initiated after December 31, 2002. Statement No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies EITF 94-3, *Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a Restructuring)* ( EITF 94-3 ). We did not elect early adoption of Statement No. 146, and recorded a special charge under EITF 94-3 for the year ended December 31, 2002 for termination costs associated with our September 2002 staff reduction.

On December 31, 2002, the Financial Accounting Standards Board issued Statement No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* ( Statement No. 148 ). Statement No. 148 amends Statement No. 123, to provide alternative methods of transition to the fair value method of accounting for stock-based employee compensation. In addition, Statement No. 148 amends the disclosure provisions of Statement No. 123 to require disclosure in the summary of significant accounting policies of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. Statement No. 148 does not amend Statement No. 123 to require companies to account for their employee stock-based awards using the fair value method. However, the disclosure provisions are required for all companies with stock-based employee compensation, regardless of whether they utilize the fair value method of accounting described in Statement No. 123 or the intrinsic value method described in APB 25. We do not intend to adopt the fair value method of accounting and we have made the disclosures required by Statement No. 148 in our consolidated financial statements.

### **Results of Operations**

During 2002, 2001 and 2000 we recorded net operating losses of \$6,460,000, \$7,690,000 and \$6,200,000, respectively. During these years, our revenue has grown from \$1,990,000 in 2000 to \$2,250,000 in 2001 to \$4,720,000 in 2002. Revenue growth has been hampered by the slow growth of the EDC market. During the last three years our operating expenses have continued to increase from \$8,190,000 in 2000 to \$9,940,000 in 2001 and \$11,180,000 in 2002. Our personnel costs, which have represented approximately 45.0% to 55.0% of our operating expenses, have increased from \$3,650,000 in 2000 to \$5,180,000 in 2001 and \$5,990,000 in 2002. During the second half of 2002, we took steps to



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reduce our annual operating costs, primarily through reductions in personnel costs, by approximately \$2,380,000.

At our current levels of revenue and conversion of backlog into revenue, we anticipate that our operating loss will be significantly reduced during 2003. However, we anticipate that we still may record a net operating loss for the year ended December 31, 2003.

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,		
	2002	2001	2000
Revenue	100.0%	100.0%	100.0%
Direct costs	38.2	79.3	80.1
Gross profit	61.8	20.7	19.9
Selling, general and administrative expenses	167.2	321.0	287.2
Special items	7.7		
Depreciation and amortization	23.8	42.3	43.5
Loss from operations	(136.9)	(342.6)	(310.8)
Other income, net	1.5	15.1	45.7
Net loss	(135.4)	(327.5)	(265.1)

*Year ended December 31, 2002 compared with year ended December 31, 2001*

Revenue for the year ended December 31, 2002 increased by 109.8% to \$4,720,000, compared to \$2,250,000 for the year ended December 31, 2001. The increase was due to greater acceptance of our DATATRAK EDC® software by clinical trial sponsors, resulting in an increase in the number of clinical trials using the DATATRAK EDC® software.

Direct costs of revenue, mainly personnel costs, were \$1,800,000 and \$1,780,000 during the years ended December 31, 2002 and 2001, respectively. Our gross profit was \$2,920,000 and \$470,000 during 2002 and 2001, respectively. A \$70,000 increase in personnel costs during 2002 was offset by a decrease in other direct costs. These other direct costs are mainly travel expenses and other costs, which are billed to our customers. We were able to leverage our prior period investments in personnel, in conjunction with our increased revenue to increase gross margin to 61.9% in 2002 compared to 20.9% in 2001. Based on our anticipated levels of revenue and our current cost structure, we anticipate that our gross margin in 2003 will meet or exceed the levels achieved in 2002.

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 9.7% to \$7,890,000 from \$7,210,000 for the years ended December 31, 2002 and 2001, respectively. The increase was primarily due to increased personnel costs of \$740,000 caused by an increase in expenses related to sales and marketing, software development and corporate office personnel.

During 2002, we recorded special charges of \$360,000. Included in special items is \$120,000 of expenses associated with our proposed acquisition of Oriam, SA, from which we withdrew in January 2003. Also, during 2002, \$240,000 of expenses related to the reduction of 20 employees were recorded. This reduction in employees, along with other decreases in payroll costs that have been implemented are expected to reduce our annual operating costs by approximately \$2,380,000 beginning in January 2003.

Depreciation and amortization expense increased to \$1,120,000 during the year ended December 31, 2002, from \$950,000 during the year ended December 31, 2001. The increase was the result of depreciating capital expenditures associated with the development of our information technology infrastructure and amortizing leasehold improvements at our new corporate headquarters.

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Other income for the year ended December 31, 2002 totaled \$70,000, compared to \$340,000 for the year ended December 31, 2001. Other income includes interest income, which decreased \$290,000 for the year ended December 31, 2002 compared to December 31, 2001 due to our use of cash to fund operating losses and other working capital needs and decreasing interest rates on our short-term investments.

Due to our loss for the year ended December 31, 2002, no income tax expense was recorded. At December 31, 2002 we had a net operating loss carryforward of approximately \$21,670,000, for United States income tax purposes, which will expire through the year 2022. We also had a net operating loss carryforward of approximately \$6,750,000 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, 2001 compared with year ended December 31, 2000*

Revenue for the year ended December 31, 2001 increased by 13.1% to \$2,250,000 compared to \$1,990,000 for the year ended December 31, 2000. Revenue growth was hampered by slower than expected development and conversion of our backlog into revenue during 2001. During the second half of 2001, we began reorganizing our sales force in order to attract new business and grow backlog.

Direct costs of revenue, mainly personnel costs, were \$1,780,000 and \$1,600,000 during the years ended December 31, 2001 and 2000, respectively. Our gross profit was \$470,000 and \$390,000 during 2001 and 2000, respectively. The 11.3% increase in direct costs was mainly the result of increased personnel costs of \$260,000 from the addition of new employees. The increase in personnel costs was partially offset by an \$80,000 decrease in other direct costs, mainly travel expenses and other costs, which are billed to our customers.

SG&A expenses increased by 26.3% to \$7,210,000 for the year ended December 31, 2001 from \$5,730,000 for the year ended December 31, 2000. The increase was primarily due to increased personnel costs of \$1,270,000 caused by an increase in sales and marketing and software development personnel.

Depreciation and amortization expense increased to \$950,000 during the year ended December 31, 2001, from \$870,000 during the year ended December 31, 2000. The increase was the result of depreciating capital expenditures associated with the development of our information technology infrastructure.

Other income for the year ended December 31, 2001 totaled \$340,000, compared to \$910,000 for the year ended December 31, 2000. Other income includes interest income, which decreased \$510,000 for the year ended December 31, 2001 compared to December 31, 2000, due to our use of cash to fund operating losses and other working capital needs, and decreasing interest rates on our short-term investments. For the year ended December 31, 2001, there was a \$50,000 decrease in foreign currency transaction adjustments compared to the year ended December 31, 2000.

Due to our loss for the year ended December 31, 2001, no income tax expense was recorded.

## **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 January 2002 we received approximately \$3,840,000 in net proceeds with the completion of our private placement of 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 upon completion of negotiated performance milestones throughout the life of the contract. We record all amounts received as a liability

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(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. Accounts receivable (net of allowance for doubtful accounts) was \$880,000 at December 31, 2002 and \$430,000 at December 31, 2001. The increase in accounts receivable was caused by our growth in revenue during 2002. Deferred revenue increased to \$900,000 at December 31, 2002 compared to \$470,000 at December 31, 2001 due to advance payments we have received in conjunction with our increased volume of contracts.

Cash and cash equivalents decreased \$490,000 during the year ended December 31, 2002. This was the result of \$5,280,000 used in operating activities, offset by \$4,800,000 provided by investing and financing activities. Cash used for operating activities resulted from the funding of net operating losses and other working capital needs. Investing activities included net proceeds of \$2,310,000 from purchases and maturities of short-term investments offset by \$1,270,000 used to purchase property and equipment. Financing activities included \$3,840,000 in cash received from our private placement of common shares.

At December 31, 2002, we had working capital of \$1,470,000, and our cash, cash equivalents and short-term investments totaled \$2,470,000. Our working capital has decreased by \$2,830,000 since December 31, 2001. The decrease was primarily the result of the \$2,740,000 decrease in our cash, cash equivalents and short-term investments, which we have relied upon to fund operations. The growth in accounts receivable was offset by the growth in deferred revenue. Changes in other current assets and liabilities caused working capital to decrease by \$110,000.

We are party to two separate lease agreements, which require us to maintain restricted cash balances. Included in our total cash, cash equivalents and short-term investments was \$220,000 of restricted cash at December 31, 2002.

We are responsible for funding the enhancement and testing of the DATATRAK EDC® software. We will 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 some revenue growth; however, we anticipate negative cash flow from operations during 2003 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 \$250,000 for the twelve months ending December 31, 2003 for the continued commercialization and enhancement of DATATRAK EDC®, which we expect to fund from existing cash and cash equivalents, maturities of short-term investments and cash flow from operations. We believe that, with the cost cutting initiatives we have undertaken and continued 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 through December 31, 2003. 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.

We have recorded net losses of \$5,280,000 in 2000, \$7,350,000 in 2001 and \$6,390,000 in 2002. Our cash, cash equivalents and short term investments were \$2,470,000 at December 31, 2002 compared with \$5,204,000 at December 31, 2001. Our viability to continue as a going concern is dependent upon customer acceptance of EDC services, management's ability to raise and/or preserve capital and ultimately, a return to profitability.

We expect to generate approximately \$5,110,000 of revenue in 2003 from our contracts in backlog as of December 31, 2002. Subsequent to year end, we have added additional contracts to backlog that we expect will generate approximately \$850,000 of additional revenue. This coupled with our staff reductions and other payroll cost savings implemented during the second half of 2002 will maintain satisfactory cash reserves during 2003. The cost cutting measures we have implemented will reduce our annual expenses by

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approximately \$2,380,000. Further, we are attempting to increase our liquidity resources through the sale of special EDC software licenses to selected customers and we continue to seek new sources of capital either through selling debt or equity securities.

We believe that our cost cutting efforts in conjunction with our growing backlog and conversion of backlog into revenue will allow us to continue as a going concern and meet our obligations over the next twelve months.

**Contractual Obligations**

The table below shows our contractual cash obligations, expressed in thousands, at December 31, 2002.

Contractual Obligations	Payments Due by Period				
	Total	Less than 1 year	1 - 3 years	4 - 5 years	After 5 years
Capital lease obligations	\$ 169	\$ 145	\$ 24	\$	\$
Operating leases	4,029	490	992	991	1,556
<b>Total contractual cash obligations</b>	<b>\$4,198</b>	<b>\$ 635</b>	<b>\$ 1,016</b>	<b>\$ 991</b>	<b>\$ 1,556</b>

**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 sales and results of operations are subject to the impact of foreign currency fluctuations. Approximately 3% of our 2002 revenue was earned in Germany by our subsidiary, DATATRAK GmbH. We manage our risk to foreign currency exchange rates 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.

**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, 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.

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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 had profitable operations.**

We began providing EDC services in 1997 and have a limited operating history upon which investors may evaluate our performance. We have recognized operating losses in each year since 1997. Our cumulative operating loss since 1997 from EDC operations totaled \$38,320,000 at December 31, 2002, and we may continue to not be profitable during future periods.

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

Although the DATATRAK EDC® software has been used in clinical trials, its continued enhancement is necessary to provide additional functionality and services to meet the ever-changing needs and expectations of our customers. Among the enhancements we have added to our software are features including electronic signatures, single user login for added security and multiple user access. 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, the timing of clinical trial sponsor decisions to conduct new clinical trials or cancel or delay ongoing trials and other factors, which could cause our revenue predictions to be incorrect. Our expense levels are based in part on our expectations as to future revenue and to a certain extent are fixed. 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.

### **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 revenues 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

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thereto 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. Because of our low level of backlog and revenue, we may lose revenues if a clinical trial sponsor decides to delay or terminate a trial in which we participate.

**We may lose revenues if any of our 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 depends 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 and other factors. 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 2002, three customers accounted for 59% 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 have a material adverse effect on the demand for our services. Several competing proposals to reform the system of health care delivery in the United States have been considered by Congress from time to time. 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. We cannot assure you that the DATATRAK® process can be kept in compliance with these guidelines and rules as they develop. 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 and in-house development efforts within large pharmaceutical companies. Any 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 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

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amounts of patient data. Potential liability may arise from a breach of contract or a loss of or unauthorized release of clinical trial data. Our financial position could be materially adversely affected if we were forced to undertake the defense of, or were found financially responsible for, claims based upon the foregoing or related risks. We maintain a \$5.0 million errors and omissions professional liability insurance policy to cover claims that may be brought against us. This coverage may not be adequate, or continue to be available to us, in the future.

**Our common Shares may be delisted if we fail to meet the continued listing requirements of Nasdaq.**

On February 12, 2003 we received a Nasdaq Staff Determination indicating that the we failed to comply with the minimum \$10 million stockholders' equity requirement for continued listing as set forth in Nasdaq Marketplace Rule 4450(a)(3), and that our common shares were subject to delisting from the Nasdaq National Market. In response to these developments, we voluntarily elected to file an application with Nasdaq to transfer the listing of our common shares from the Nasdaq National Market to the Nasdaq SmallCap Market. Our transfer application was accepted and our common shares began trading on the Nasdaq SmallCap Market on March 26, 2003. As a Nasdaq SmallCap Market listed company, we must continue to comply with the continued listing standards of the Nasdaq SmallCap Market, and any further events of noncompliance would subject us to further delisting actions by Nasdaq. If we were delisted from Nasdaq, we would pursue an alternative trading venue. However, if this occurs, it would make it more difficult for us to raise funds through the sale of our securities. In addition, it may make it more difficult for an investor to dispose of, or to obtain accurate quotations of, our common shares and negatively impact the market price.

**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 long- and 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, 2002 would have resulted in a \$40,000 change in our interest income during the year.

**Foreign Currency Risk**

Our foreign sales and results of operations are subject to the impact of foreign currency fluctuations. Approximately 3% of our 2002 revenue was earned in Germany by our subsidiary, DATATRAK GmbH. We manage our risk to foreign currency exchange rates 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. A 1.0% fluctuation in the exchange rate between United States dollars and the Euro at December 31, 2002 would have resulted in a \$55,000 change in the foreign currency translation amount recorded on our balance sheet and a \$170,000 change in our net loss for the year ended December 31, 2002 due to foreign currency transactions.

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**ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

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Quarterly results of operations for the year ended December 31, 2002 are included in Note 17 of the Consolidated Financial Statements.

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

None.

**PART III**

**ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

The information appearing under the captions "Election of Directors" and "Section 16(a) Beneficial Ownership Reporting Compliance" in the Company's definitive Proxy Statement to be used in connection with the Annual Meeting of Shareholders to be held on June 3, 2003 (the "2003 Proxy Statement") is incorporated herein by reference. Information regarding the executive officers of the Company is included as Item 4A of Part I of this Annual Report on Form 10-K as permitted by Instruction 3 to Item 401(b) of Regulation S-K.

**ITEM 11. EXECUTIVE COMPENSATION**

The information appearing under the captions "Compensation of Directors", "Executive Officer Compensation" and "Compensation Committee Interlocks and Insider Participation" in the 2003 Proxy Statement is incorporated herein by reference.

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

The information appearing under the captions "Executive Officer Compensation" and "Security Ownership of Principal Holders and Management" in the 2003 Proxy Statement is incorporated herein by reference.



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**ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

To the extent applicable, the information appearing under the caption "Certain Transactions" in the 2003 Proxy Statement is incorporated herein by reference.

**ITEM 14. CONTROLS AND PROCEDURES**

Within 90 days prior to the date of the filing of this report, the Company's Chief Executive Officer and Chief Financial Officer conducted an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures pursuant to Exchange Act Rule 13a-14. Based upon that evaluation such officers concluded that the Company's disclosure controls and procedures are effective to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms.

There have been no significant changes in the Company's internal controls or in other factors that could significantly affect these controls subsequent to the date of the evaluation referred to above.

**PART IV**

**ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K**

(a)(1) Financial Statements

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

(a)(2) Financial Statement Schedules

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

(a)(3) Exhibits

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

(b) Reports on Form 8-K.

No reports were filed on Form 8-K during the last quarter of the period covered by this Annual Report on Form 10-K other than the following:

Current Report on Form 8-K dated December 17, 2002 furnishing under Item 9, a press release pursuant to Regulation FD.

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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

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Jeffrey A. Green  
President and Chief Executive Officer

Date: March 27, 2003

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

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

Date: March 27, 2003



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**CERTIFICATIONS**

I, Jeffrey A. Green, Chief Executive Officer, DATATRAK International, Inc., certify that:

1. I have reviewed this annual report on Form 10-K of DATATRAK International, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 27, 2003

/s/ Jeffrey A. Green

Jeffrey A. Green,  
President and Chief Executive Officer

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I, Terry C. Black, Chief Financial Officer, DATATRAK International, Inc., certify that:

1. I have reviewed this annual report on Form 10-K of DATATRAK International, Inc.;
2. Based on my knowledge, this annual report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this annual report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-14 and 15d-14) for the registrant and we have:
  - a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this annual report (the "Evaluation Date"); and
  - c) presented in this annual report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date;
5. The registrant's other certifying officers and I have disclosed, based on our most recent evaluation, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):
  - a) all significant deficiencies in the design or operation of internal controls which could adversely affect the registrant's ability to record, process, summarize and report financial data and have identified for the registrant's auditors any material weaknesses in internal controls; and
  - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls; and
6. The registrant's other certifying officers and I have indicated in this annual report whether there were significant changes in internal controls or in other factors that could significantly affect internal controls subsequent to the date of our most recent evaluation, including any corrective actions with regard to significant deficiencies and material weaknesses.

Date: March 27, 2003

/s/ Terry C. Black

Terry C. Black,  
Vice President of Finance, Chief Financial Officer,  
Treasurer and Assistant Secretary

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**REPORT OF INDEPENDENT AUDITORS**

The Board of Directors and Shareholders  
DATATRAK International, Inc.

We have audited the accompanying consolidated balance sheets of DATATRAK International, Inc. and subsidiaries (the Company) as of December 31, 2002 and 2001, and the related consolidated statements of operations, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2002. 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 auditing standards generally accepted in the United States. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of DATATRAK International, Inc. and subsidiaries at December 31, 2002 and 2001, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2002, in conformity with accounting principles generally accepted in the United States.

ERNST & YOUNG LLP

Cleveland, Ohio  
January 31, 2003,  
except for Note 18, as to which the date is  
March 26, 2003

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**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES  
CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2002	2001
<b>Assets</b>		
Current assets		
Cash and cash equivalents	\$ 1,682,642	\$ 2,174,445
Short-term investments	785,277	3,029,582
Accounts receivable, net	883,584	429,911
Taxes receivable	4,500	197
Notes receivable - current	3,935	59,164
Prepaid expenses	157,022	314,142
	<u>3,516,960</u>	<u>6,007,441</u>
Property and equipment		
Equipment	5,043,099	4,297,065
Leasehold improvements	604,322	135,669
	<u>5,647,421</u>	<u>4,432,734</u>
Less accumulated depreciation	3,898,356	2,858,523
	<u>1,749,065</u>	<u>1,574,211</u>
Other assets		
Notes receivable - long term		4,487
Other assets	39,549	47,431
	<u>39,549</u>	<u>51,918</u>
	<u>5,305,574</u>	<u>7,633,570</u>
<b>Liabilities and Shareholders' Equity</b>		
Current liabilities		
Accounts payable	\$ 97,938	\$ 253,095
Current portion of capital lease obligation	138,388	129,417
Accrued expenses	913,143	864,611
Deferred revenue	901,509	469,275
	<u>2,050,978</u>	<u>1,716,398</u>
Capital lease obligation, less current portion	23,979	162,367
Shareholders' equity		
Serial Preferred Shares, without par value; authorized 1,000,000 shares; none issued		
Common shares, without par value, authorized 15,000,000 shares; issued 8,563,836 shares as of December 31, 2002 and 6,591,322 as of December 31, 2001; outstanding 5,263,836 shares as of December 31, 2002 and 3,291,322 shares as of December 31, 2001		
	53,868,303	50,372,239
Treasury shares, 3,300,000 shares at cost	(20,188,308)	(20,188,308)
Common share warrants	357,589	
Accumulated deficit	(30,732,049)	(24,341,439)
Foreign currency translation	(74,918)	(87,687)
	<u>(74,918)</u>	<u>(87,687)</u>



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Total shareholders' equity	3,230,617	5,754,805
Total liabilities and shareholders' equity	\$ 5,305,574	\$ 7,633,570

*See accompanying notes.*

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

	For the Year Ended December 31,		
	2002	2001	2000
Revenue	\$ 4,720,912	\$ 2,245,631	\$ 1,993,785
Direct costs	1,803,671	1,779,501	1,596,355
	2,917,241	466,130	397,430
Gross profit	2,917,241	466,130	397,430
Selling, general and administrative expenses	7,893,208	7,209,789	5,725,846
Special items	363,964		
Depreciation and amortization	1,122,528	949,770	867,484
	(6,462,459)	(7,693,429)	(6,195,900)
Loss from operations	(6,462,459)	(7,693,429)	(6,195,900)
Other income (expense):			
Interest income	89,196	382,483	888,385
Interest expense	(17,347)	(19,491)	
Other income (expense)		(23,796)	23,768
	\$(6,390,610)	\$(7,354,233)	\$(5,283,747)
Net loss	\$(6,390,610)	\$(7,354,233)	\$(5,283,747)
Basic and diluted net loss per share	\$ (1.22)	\$ (2.23)	\$ (1.61)
Weighted average shares outstanding	5,237,425	3,290,514	3,290,322

*See accompanying notes.*

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**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES  
CONSOLIDATED STATEMENTS OF SHAREHOLDERS EQUITY**

	Common Shares		Treasury Shares		Common Share Warrants	
	Number of Shares	Stated Amount	Number of Shares	Cost	Number of Shares	Cost
<b>Balance at January 1, 2000</b>	3,290,322	\$ 50,236,553	3,300,000	\$(20,188,308)		\$
Stock compensation		120,114				
Comprehensive loss:						
Foreign currency translation						
Net loss						
Comprehensive loss						
<b>Balance at December 31, 2000</b>	3,290,322	50,356,667	3,300,000	(20,188,308)		
Exercise of common share options	1,000	800				
Stock compensation		14,772				
Comprehensive loss:						
Foreign currency translation						
Net loss						
Comprehensive loss						
<b>Balance at December 31, 2001</b>	3,291,322	50,372,239	3,300,000	(20,188,308)		
Private placement of common shares	1,922,514	3,459,792				
Issuance of common share warrants					192,252	\$ 357,589
Exercise of common share options	50,000	7,500				
Stock compensation		28,772				
Comprehensive loss:						
Foreign currency translation						
Net loss						
Comprehensive loss						
<b>Balance at December 31, 2002</b>	5,263,836	\$ 53,868,303	3,300,000	\$(20,188,308)	192,252	\$ 357,589

[Additional columns below]

[Continued from above table, first column(s) repeated]

**Retained Earnings (Accumulated)**      **Foreign Currency Translation**

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	Deficit)	Adjustments	Total
<b>Balance at January 1, 2000</b>	\$(11,703,459)	\$(38,789)	\$ 18,305,997
Stock compensation			120,114
Comprehensive loss:			
Foreign currency translation		(38,395)	(38,395)
Net loss	(5,283,747)		(5,283,747)
			<u>(5,322,142)</u>
<b>Balance at December 31, 2000</b>	(16,987,206)	(77,184)	13,103,969
Exercise of common share options			800
Stock compensation			14,772
Comprehensive loss:			
Foreign currency translation		(10,503)	(10,503)
Net loss	(7,354,233)		(7,354,233)
			<u>(7,364,736)</u>
<b>Balance at December 31, 2001</b>	(24,341,439)	(87,687)	5,754,805
Private placement of common shares			3,459,792
Issuance of common share warrants			357,589
Exercise of common share options			7,500
Stock compensation			28,772
Comprehensive loss:			
Foreign currency translation		12,769	12,769
Net loss	(6,390,610)		(6,390,610)
			<u>(6,377,841)</u>
<b>Balance at December 31, 2002</b>	\$(30,732,049)	\$(74,918)	\$ 3,230,617

*See accompanying notes*

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

	For the Year Ended December 31,		
	2002	2001	2000
<b>Operating Activities</b>			
Net loss	\$ (6,390,610)	\$ (7,354,233)	\$ (5,283,747)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,122,528	949,770	867,484
Accretion of discount on investments	(61,571)	(307,600)	(748,790)
Stock compensation	14,772	14,772	120,114
Other	(23,838)	18,000	49,373
Changes in operating assets and liabilities:			
Accounts and taxes receivable	(433,876)	291,629	(401,862)
Prepaid expenses	157,120	(73,430)	21,924
Other assets	7,882	(39,049)	551
Accounts payable and accrued expenses	(106,625)	74,554	(103,284)
Deferred revenue	432,234	130,396	307,919
Net cash used in operating activities	(5,281,984)	(6,295,191)	(5,170,318)
<b>Investing Activities</b>			
Purchases of property and equipment	(1,273,687)	(689,718)	(1,029,494)
Maturities of short-term investments	12,881,000	28,035,000	48,385,285
Purchases of short-term investments	(10,575,124)	(21,100,130)	(42,718,276)
Other	1,095		
Net cash provided by investing activities	1,033,284	6,245,152	4,637,515
<b>Financing Activities</b>			
Payments under capital lease obligation	(129,417)	(101,416)	
Repayment (issuance) of notes receivable	59,716	19,070	(19,304)
Proceeds from issuance of shares	3,838,881	800	
Net cash provided by (used in) financing activities	3,769,180	(81,546)	(19,304)
Effect of exchange rate on cash	(12,283)	(77,214)	(26,052)
Decrease in cash and cash equivalents	(491,803)	(208,799)	(578,159)
Cash and cash equivalents at beginning of year	2,174,445	2,383,244	2,961,403
Cash and cash equivalents at end of year	\$ 1,682,642	\$ 2,174,445	\$ 2,383,244
Cash paid during the year for interest	\$ 17,347	\$ 19,491	\$
Net cash paid during the year for income taxes	\$	\$	\$ 103,795

*See accompanying notes.*

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**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES  
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS  
For the Years Ended December 31, 2002, 2001 and 2000**

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**1. Accounting Policies**

*Description of Business*

DATATRAK International, Inc. ( DATATRAK or the Company ) and its wholly-owned subsidiary, DATATRAK GmbH, are Application Service Providers ( ASPs ) that provide 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 other wholly-owned subsidiary, DATATRAK Inc., is an inactive holding company with no employees that does not provide ASP or EDC services.

*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 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 contract will not result in a material adjustment to the revenue or costs previously recognized. DATATRAK is also a seller and licensor of software. Generally, revenue is recognized upon delivery of sold software. Licensing revenue is recognized ratably over the life of the license. To date, DATATRAK has not recognized any revenue from software sales.

*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.

*Short-term Investments*

Short-term investments are comprised of obligations of U.S. government agencies and U.S. 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.

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**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Continued**  
**For the Years Ended December 31, 2002, 2001 and 2000**

---

*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 \$1,120,000, \$950,000 and \$870,000 for 2002, 2001 and 2000, respectively.

Included in equipment at December 31, 2002 and 2001, is equipment under capital lease recorded at a cost of \$390,000. Amortization expense related to this equipment was \$130,000 and \$100,000 in 2002 and 2001. Accumulated amortization related to this equipment was \$230,000 and \$100,000 at December 31, 2002 and 2001, respectively.

*Impairment of Long-Lived Assets*

The Company evaluates impairment of long-lived assets in accordance with Financial Accounting Standards Board Statement 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 Opinion No. 25, *Accounting for Stock Issued to Employees* ( APB No. 25 ).

On December 31, 2002, the FASB issued Statement No. 148, *Accounting for Stock-Based Compensation Transition and Disclosure* ( Statement No. 148 ). Statement No. 148 amends FASB Statement No. 123, *Accounting for Stock-Based Compensation* ( Statement No. 123 ), to provide alternative methods of transition to the fair value method of accounting for stock-based employee compensation. In addition, Statement No. 148 amends the disclosure provisions of Statement No. 123 to require disclosure in the summary of significant accounting policies of the effects of an entity's accounting policy with respect to stock-based employee compensation on reported net income and earnings per share in annual and interim financial statements. Statement No. 148 does not amend Statement No. 123 to require companies to account for their employee stock-based awards using the fair value method. However, the disclosure provisions are required for all companies with stock-based employee compensation, regardless of whether they utilize the fair method of accounting described in Statement No. 123 or the intrinsic value method in APB No. 25. The Company does not intend to adopt the fair value method of accounting and it has made the disclosures required by Statement No. 148 in its consolidated financial statements.

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**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Continued**  
**For the Years Ended December 31, 2002, 2001 and 2000**

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*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 \$280,000, \$380,000 and \$270,000 for 2002, 2001 and 2000, respectively.

*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 Statement of Financial Accounting Standards 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 were \$60,000, \$110,000 and \$70,000 at December 31, 2002, 2001 and 2000, respectively. Amortization expense related to capitalized software costs was \$50,000, \$120,000 and \$330,000 in 2002, 2001 and 2000, respectively.

Research and development expenses included in selling, general and administrative expenses were \$1,680,000, \$1,660,000 and \$890,000 in 2002, 2001 and 2000, 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*

In June 2002, the Financial Accounting Standards Board (FASB) issued Statement No. 146, Accounting for Costs Associated with Exit or Disposal Activities (Statement No. 146), which is effective for exit or disposal activities that are initiated after December 31, 2002. Statement No. 146 addresses financial accounting and reporting for costs associated with exit or disposal activities and nullifies EITF 94-3, Liability Recognition for Certain Employee Termination Benefits and Other Costs to Exit an Activity (including Certain Costs Incurred in a



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**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Continued**  
**For the Years Ended December 31, 2002, 2001 and 2000**

Restructuring) ( EITF 94-3 ). The Company did not elect early adoption of Statement No. 146, and recorded a special charge under EITF 94-3 for the year ended December 31, 2002 (See Note 16).

*Reclassification*

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

**2. Notes Receivable**

The Company has an employee loan outstanding in the amount of \$3,935 and \$10,966 at December 31, 2002 and 2001, respectively, which is scheduled to be paid in full during 2003. The loan bears interest at 5.5%, compounded monthly.

The Company had loans outstanding to an officer in the amount of \$52,685 at December 31, 2001. The loans bore interest at 5.0%, compounded monthly, and were due on demand. The loans were paid in full during 2002.

**3. Short-term Investments**

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

	December 31, 2002		December 31, 2001	
	Cost	Amortized Cost	Cost	Amortized Cost
Obligations of U.S. government agencies	\$ 250,543	\$ 250,688	\$ 502,904	\$ 503,712
U.S. corporate obligations	533,620	534,589	2,507,016	2,525,870
	\$ 784,163	\$ 785,277	\$ 3,009,920	\$ 3,029,582

**4. Accounts Receivable**

Accounts receivable consist of the following:

	December 31,	
	2002	2001
Trade accounts receivable:		
Billed	\$ 883,799	\$ 342,228
Unbilled	19,711	148,066
Total trade accounts receivable	903,510	490,294
Other	20,474	4,117
Allowance for doubtful accounts	(40,400)	(64,500)
	\$ 883,584	\$ 429,911



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**DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES**  
**NOTES TO CONSOLIDATED FINANCIAL STATEMENTS Continued**  
**For the Years Ended December 31, 2002, 2001 and 2000**

Movement of the allowance for doubtful accounts is as follows:

	Year ended December 31,		
	2002	2001	2000
Balance at beginning of year	\$ 64,500	\$46,500	\$30,000
Provision for uncollectible accounts	28,000	28,000	16,500
Uncollectible accounts written off	(42,100)		
	\$ 40,400	\$64,500	\$46,500
	\$ 40,400	\$64,500	\$46,500

**5. Accrued Expenses**

Accrued expenses consist of the following:

	December 31,	
	2002	2001
Office rent	98,511	34,174
Payroll and other employee costs	568,458	552,737
Professional fees	187,468	227,043
Other	58,706	50,657
	\$913,143	\$864,611
	\$913,143	\$864,611

**6. Income Taxes**

Due to its net losses, the Company had no federal, state or local income tax expense in 2002, 2001 and 2000.

A reconciliation of income tax benefit at the United States Federal statutory rate to the effective income tax rate is as follows:

	Year ended December 31,		
	2002	2001	2000
Income tax benefit at the United States statutory rate	\$(2,172,800)	\$(2,500,400)	\$(1,796,500)
Non U.S. income taxes	80,000	53,000	61,600
Change in valuation allowance	2,335,000	2,483,000	1,779,000
Allowances, accruals and other	(242,200)	(35,600)	(44,100)
	\$	\$	\$
	\$	\$	\$



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At December 31, 2002 the Company had a net operating loss carryforward of approximately \$21,670,000 for United States income tax purposes, which will expire through the year 2022. The Company also had a net operating loss carryforward of approximately \$6,750,000 for German income tax purposes with no expiration date. The significant components of the Company's deferred tax assets (liabilities) are as follows:

	December 31,	
	2002	2001
Deferred tax assets (liabilities):		
U.S. net operating loss carryforwards	\$ 7,369,000	\$ 5,852,000
Non U.S. net operating loss carryforwards	2,566,000	1,717,000
Alternative minimum tax credit	92,000	92,000
Allowances and accruals	174,000	218,000
Depreciation and amortization	(89,000)	(102,000)
	<u>10,112,000</u>	<u>7,777,000</u>
Valuation allowance	(10,112,000)	(7,777,000)
	<u>\$</u>	<u>\$</u>
Net deferred tax assets recorded	<u>\$</u>	<u>\$</u>

**7. Operating Leases**

The Company leases certain office equipment and space. Rent expense relating to these operating leases was approximately \$480,000, \$390,000 and \$280,000 in 2002, 2001 and 2000, respectively. Future minimum lease payments for the Company under noncancelable operating leases as of December 31, 2002 are as follows:

Year ending December 31,	Amount
2003	\$ 490,000
2004	490,000
2005	500,000
2006	510,000
2007	480,000
Subsequent to 2007	1,560,000
	<u>\$4,030,000</u>

**8. 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 approximately \$3.8 million 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 are fully vested as of the grant date and expire five years from the date of grant. 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 private placement of common shares.

*Serial Preferred Shares*

At December 31, 2002 and 2001, the Company had 1,000,000 Serial Preferred Shares, without par value, authorized, with none outstanding.

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*Treasury Shares*

At December 31, 2002 and 2001, the Company held 3,300,000 of its common shares in treasury at a cost of \$20,188,308.

**9. Share Option Plans**

The Company has five share option plans. At December 31, 2002, the Company had reserved 1,733,375 common shares for the exercise of common share options. The Company has granted 1,382,823 options to purchase common shares to employees, directors and others. There are 350,552 options to purchase common shares available for future grants. The weighted average contractual life of all options outstanding was 6.7 years as of December 31, 2002. The range of exercise prices for all options outstanding at December 31, 2002 was \$0.15 to \$10.75.

The Amended and Restated 1992 Share Incentive Plan ( 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 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, 2002 there were 77,000 options outstanding under the 1992 Plan with exercise prices ranging from \$0.15 to \$4.15, all of which were 100% vested. These options had a weighted average contractual life of 2.1 years and a weighted average exercise price of \$2.07. There will be no future grants of options under the 1992 Plan.

The Amended and Restated 1994 Directors' Share Option Plan ( 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 Director Plan expire ten years after the grant date. At December 31, 2002 there were 6,667 options outstanding under the Director Plan with exercise prices ranging from \$0.80 to \$9.60, all of which were 100% vested. These options had a weighted average contractual life of 2.5 years and a weighted average exercise price of \$5.17. There will be no future grants of options under the Director Plan.

The Amended and Restated 1996 Outside Directors' Stock Option Plan, as amended ( 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 date. 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, 2002 there were 66,500 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 5.3 years and a weighted average exercise price of \$4.84. There will be no future grants of options under the 1996 Director Plan.

The Amended and Restated 1996 Key Employees and Consultants Stock Option Plan, as amended ( 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

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compensation expense related to these common share options of \$14,772, \$14,772 and \$14,514 in 2002, 2001 and 2000, respectively. If all options vest, additional compensation expense of \$16,000 will be recognized through 2004. 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. Vesting of options awarded under the 1996 Plan is determined by the Company's Compensation Committee, as appointed by the Board of Directors, and all options granted under the 1996 Plan expire ten years after the grant date. At December 31, 2002 there were 654,115 options outstanding under the 1996 Plan with exercise prices ranging from \$2.00 to \$10.75, of which 324,031 were 100% vested. These options had a weighted average contractual life of 7.1 years and a weighted average exercise price of \$4.02.

During 1999, the Company established the 1999 Outside Director Stock Option Plan ( 1999 Plan ). The 1999 Plan provides for the granting of a maximum of 250,000 options to purchase common shares to outside directors of the Company. In 1999, the Company's Board of Directors approved the granting of a total of 72,500 common share options at exercise prices of \$3.63 and \$3.75 per share. The Company's shareholders approved these option grants, at exercise prices below the market value of a common share, on the approval date, in 2000. The Company recognized compensation expense related to these common share options of \$105,600 in 2000. No further compensation expense will be recorded related to these common share options. All other options granted under the 1999 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 1999 Plan expire ten years after the grant date. At December 31, 2002 there were 222,500 options outstanding under the 1999 Plan with exercise prices ranging from \$2.00 to \$5.19, all of which were 100% vested. These options had a weighted average contractual life of 7.5 years and a weighted average exercise price of \$3.64.

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

	Year ended December 31,					
	2002		2001		2000	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at beginning of Period	1,095,083	\$ 3.73	919,242	\$ 4.00	666,089	\$ 3.83
Granted	82,270	2.78	176,841	2.30	270,434	4.58
Exercised	(50,000)	0.15	(1,000)	0.80		
Cancelled	(100,571)	3.56			(17,281)	6.33
Outstanding at end of period	<u>1,026,782</u>	<u>\$ 3.85</u>	<u>1,095,083</u>	<u>\$ 3.73</u>	<u>919,242</u>	<u>\$ 4.00</u>
Exercisable at end of period	<u>696,698</u>	<u>\$ 4.04</u>	<u>609,619</u>	<u>\$ 2.95</u>	<u>354,350</u>	<u>\$ 3.20</u>

**10. Stock Based Compensation**

The Company has elected to follow APB 25 and related interpretations in accounting for its employee and director stock options. As discussed below, the alternative fair value accounting provided for under Statement No. 123, requires use of option valuation models that were not developed for use in valuing employee stock options. Under APB 25 compensation expense has been recognized for all options granted at less than the fair market value of the common shares on the date of grant.





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Pro forma information regarding net income and earnings per share is required by Statement No. 123, which also requires that the information be determined as if the Company has accounted for its stock options granted subsequent to December 31, 1994 under the fair value method of that Statement. The following assumptions were used to determine the fair value for these options using a Black-Scholes option pricing model.

	Year ended December 31		
	2002	2001	2000
Risk free interest rate	4.3%	4.9%	6.5%
Volatility factor of the expected market price of the common shares	1.36	0.66	0.57
Dividend yield	0.0%	0.0%	0.0%
Weighted-average expected life of the option	7 years	7 years	7 years
Weighted-average fair value per share of options granted	\$2.53	\$ 1.45	\$3.34

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. Because the Company's stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management's opinion, the existing models do not necessarily provide a reliable single measure of the fair value of its stock options.

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 Statement No. 123. The Company's pro forma information follows:

	Year ended December 31,		
	2002	2001	2000
Pro forma net loss	\$(6,767,086)	\$(7,844,762)	\$(5,805,030)
Pro forma basic and diluted loss per share	\$ (1.36)	\$ (2.65)	\$ (1.88)

**11. 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 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 2002, 2001 or 2000.

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**12. 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
<b>Revenue:</b>			
2002	\$ 4,598,769	\$ 122,143	\$ 4,720,912
2001	1,785,745	459,886	2,245,631
2000	1,541,921	451,864	1,993,785
<b>Net loss:</b>			
2002	(3,299,207)	(3,091,403)	(6,390,610)
2001	(5,131,023)	(2,223,210)	(7,354,233)
2000	(2,995,743)	(2,288,004)	(5,283,747)
<b>Long-lived assets at December 31,</b>			
2002	1,541,080	207,985	1,749,065
2001	1,365,426	208,785	1,574,211

*Major Customers*

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

Customer	Year ended December 31,		
	2002	2001	2000
Aventis Pharmaceuticals	29%	22%	27%
Control Delivery Systems	20%	23%	*
CV Therapeutics	*	21%	*
Quintiles	*	11%	52%
Daiichi Pharmaceutical	10%	*	0%
All other customers	39%	21%	10%

\* Less than 10% of revenue.

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**13. Net Loss Per Share**

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

	Year Ended December 31,		
	2002	2001	2000
Net loss used in the calculation of basic and diluted earnings per share	\$(6,390,610)	\$(7,354,233)	\$(5,283,747)
Denominator for basic and diluted net loss per share weighted average common shares outstanding	5,237,425	3,290,514	3,290,322
Basic and diluted net loss per share	\$ (1.22)	\$ (2.23)	\$ (1.61)
Common share options and warrants excluded from the computation of diluted net loss per share because they would have an antidilutive effect on net loss per share	1,219,034	1,095,083	919,242

**14. Capital Lease Obligation**

The Company is party to an agreement with an unaffiliated third party to lease certain computer equipment. The lease has been recorded as a capital lease. Future minimum lease payments under the capital lease obligation as of December 31, 2002 are as follows:

**Twelve months ending December 31,**

2003	145,089
2004	24,181
	169,270
Less amounts representing interest	6,903
	\$ 162,367

**15. Restricted Cash**

Terms of the Company's capital lease agreement (see Note 14) require the Company to maintain a restricted cash balance equal to the outstanding balance payable on the lease. The restricted cash balance was \$162,367 at December 31, 2002.

In addition, 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 59,082 Euros with the bank. The U.S. dollar equivalent of this amount was \$61,935 at December 31, 2002.

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DATATRAK's total restricted cash balance was \$224,302 at December 31, 2002.

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**16. Special Items**

During the third quarter of 2002, the Company recorded a special charge of \$238,320. 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, 2002, \$204,665 of these costs had been paid. The unpaid balance of \$33,655 is included in accrued expenses at December 31, 2002 and will be paid prior to March 31, 2003.

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 \$125,644 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.

**17. Quarterly Data (Unaudited)**

Selected quarterly data is as follows (in thousands):

	Year Ended December 31, 2002			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenue	\$ 816	\$ 1,145	\$ 1,505	\$ 1,255
Gross profit	382	639	1,035	861
Loss from operations	(1,800)	(1,757)	(1,800)	(1,105)
Net loss	(1,771)	(1,736)	(1,785)	(1,099)
Basic and diluted net loss per share	(0.34)	(0.33)	(0.34)	(0.21)

	Year Ended December 31, 2001			
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenue	\$ 673	\$ 400	\$ 477	\$ 696
Gross profit (loss)	243	(29)	45	207
Loss from operations	(1,730)	(1,839)	(2,027)	(2,097)
Net loss	(1,591)	(1,736)	(1,967)	(2,060)
Basic and diluted net loss per share	(0.48)	(0.53)	(0.60)	(0.63)

The Company recorded special items charges of \$363,964 during the third quarter of 2002. As described further in Note 16, these charges were for costs associated with employee terminations and the Company's proposed acquisition of Oriam, SA.

**18. Subsequent Events**

On February 12, 2003, the Company received a Nasdaq Staff Determination indicating that the Company failed to comply with the minimum \$10 million stockholders' equity requirement for continued listing as set forth in Nasdaq Marketplace Rule 4450(a)(3), and that its securities were, therefore, subject to delisting from the Nasdaq National Market. The Company voluntarily elected to file an application with Nasdaq to transfer the listing of its securities from the Nasdaq National Market to the Nasdaq SmallCap Market. The transfer application was accepted and the Company's common shares began trading on the Nasdaq SmallCap Market on March 26, 2003.



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**19. Results of Operations**

The Company recorded net losses of \$5,280,000 in 2000, \$7,350,000 in 2001 and \$6,390,000 in 2002. As of December 31, 2002, the Company's cash, cash equivalents and short term investments were \$2,470,000. The Company's viability to continue as a going concern is dependent upon customer acceptance of EDC services, management's ability to raise and/or preserve capital and ultimately, a return to profitability.

The Company expects to generate approximately \$5,110,000 of revenue in 2003 from contracts in backlog as of December 31, 2002. Subsequent to year end, additional contracts have been added to backlog that are expected to generate approximately \$850,000 of additional revenue. This coupled with staff reductions and other payroll cost savings implemented during the second half of 2002 will maintain satisfactory cash reserves during 2003. The cost cutting measures the Company has implemented will reduce its annual expenses by approximately \$2,380,000. Further, the Company is attempting to increase its liquidity resources through the sale of special EDC software licenses to selected customers and the Company continues to seek new sources of capital either through selling debt or equity securities.

Management believes that its cost cutting efforts in conjunction with DATATRAK's growing backlog and conversion of backlog into revenue will allow the Company to continue as a going concern and meet its obligations over the next twelve months.



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<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>	<b><u>Page</u></b>
3.1	Fifth Amended and Restated Articles of Incorporation	
3.2	Certificate of Amendment to the Fifth Amended and Restated Articles of Incorporation dated April 14, 1999	
3.3	Certificate of Amendment to the Fifth Amended and Restated Articles of Incorporation dated September 22, 1999	(1)
3.4	Third Amended and Restated Code of Regulations	
3.5	Certificate of Amendment to the Third Amended and Restated Code of Regulations	
4.1	Specimen Certificate of the Company's Common Shares, without par value	(2)
4.2	Second Amended and Restated Registration Agreement, dated July 25, 1994, as amended on June 1, 1995 and February 5, 1996	(3)
10.1	Amended and Restated 1994 Directors' Share Option Plan*	(4)
10.2	Amendment to the Amended and Restated 1994 Directors' Share Option Plan*	
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*	
10.5	Amendment No. 2 to the Amended and Restated 1996 Outside Directors' Stock Option Plan*	
10.6	Amendment to the Amended and Restated 1996 Outside Directors' Stock Option Plan*	
10.7	Amended and Restated 1992 Share Incentive Plan*	(4)
10.8	Amendment to the Amended and Restated 1992 Share Incentive Plan*	
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*	
10.11	Amendment No. 2 to the Amended and Restated 1996 Key Employees' and Consultants Stock Option Plan*	
10.12	Amendment No. 3 to the Amended and Restated 1996 Key Employees' and Consultants Stock Option Plan*	
10.13	Amendment to the Amended and Restated 1996 Key Employees' and Consultants Stock Option Plan*	
10.14	1999 Outside Director Stock Option Plan*	

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<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>	<b><u>Page</u></b>
10.15	Amendment to the 1999 Outside Director Stock Option Plan*	
10.16	Form of Indemnification Agreement*	(3)
10.17	Employment Agreement between the Company and Jeffrey A. Green, dated February 5, 2001*	(5)
10.18	Employment Agreement between the Company and Terry C. Black, dated February 5, 2001*	(5)
10.19	Employment Agreement between the Company and Marc J. Shlaes dated March 5, 2003*	
10.20	Managing Director Employment Agreement between the Company and Wolfgang Summa, dated December 29, 2000*	(5)
10.21	DATATRAK International, Inc. Retirement Savings Plan*	(6)
21.1	Subsidiaries of the Company	
23.1	Consent of Ernst & Young LLP	

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\* Management compensatory plan or arrangement.

- (1) Incorporated herein by reference to the Company's Form S-8 Registration Statement filed on November 10, 1999 (File No. 333-90699).
- (2) Incorporated herein by reference to the Company's Form 10-K for the year ended December 31, 1999 (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).