DATATRAK INTERNATIONAL INC
Form 10-K
March 19, 2004

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2003

OR

o 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.

Yesx Noo

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. o

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

Yeso Nox

As of June 30, 2003, the aggregate market value of the 4,807,992 common shares then outstanding, which together constituted all of the voting shares of the registrant, held by non-affiliates was $18,703,089 (based upon the closing price of $3.89 per common share on the Nasdaq SmallCap Market on June 30, 2003). For purposes of this calculation, the registrant deems the common shares held by all of its Directors and executive officers to be the common shares held by affiliates. As of February 29, 2004, the registrant had 6,039,553 common shares, without par value, issued and outstanding.

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 2, 2004 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, 2003.

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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, as a site management organization, to various clinical trial sponsors. We currently operate in one business segment 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 $608,000. 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 $3,831,000 in net proceeds from the successful completion of a private placement of 1,922,514 of our common shares at a purchase price of $2.25 per share. In August 2003, we completed a second private placement of 602,500 of our common shares, at a purchase price of $4.00 per share, from which we received net proceeds of $2,239,000. The proceeds of these two private placements 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.

During the second half of 2002, we took steps to streamline our cost structure primarily through staff reductions and payroll cost savings in order to allow us to lower our break-even point, and to potentially achieve profitability more quickly than previously anticipated. The benefits of these cost cutting steps along with our growth in revenue can be seen in our results of operations for 2003. During 2003, we significantly reduced our net loss to $1,049,000 compared to losses of $6,391,000 and $7,354,000 in 2002 and 2001, respectively.

Overview of the Clinical Research Industry

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

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and development expenditures. Sponsors of clinical trials have attempted to create process efficiencies, control fixed costs and expand capacity by outsourcing clinical research activities.

DATATRAK Software and Services

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

DATATRAK EDC® was developed to provide clinical research data to sponsors of clinical research trials faster and more efficiently than other forms of information-processing that utilize paper. We believe that automating data entry and review procedures can save time in the drug development and medical device approval process. The DATATRAK EDC® software and its earlier versions have supported many international clinical trials involving thousands of clinical research sites and tens of thousands of patients in over 40 countries. Our product suite has been utilized in the clinical development of 14 separate drugs that have received regulatory approval from either the U.S. Food and Drug Administration (FDA) or counterpart regulatory bodies in Europe.

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 timelier and more efficient basis while also enhancing the quality of the data. In addition to providing technology, we are also a service business that offers EDC and clinical trial data management capabilities across numerous research sites. Our objective is to improve the traditional process of collecting clinical research and noninterventional health care data by providing cleaner data more quickly than what is available in a paper environment.

The DATATRAK EDC® system consists of numerous modules designed for flexible adaptation to the clinical research process. We initially provide a set of electronic data forms that can be modeled to suit the needs of each particular clinical trial. Each form is then made available through data entry capability to each research site participating in the clinical trial via the Internet 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 database. Under this model, research data is collected more quickly and with greater accuracy than with physical review of paper reports.

We are continually enhancing and testing the DATATRAK EDC® software and developing the DATATRAK® process. Recent initiatives and enhancements to the DATATRAK EDC® software include a new portal of entry for all of DATATRAK s future clinical trials called StudyTrak , our Technology Transfer program which will allow customers to design their own EDC spreadsheets and a joint venture EDC certification program known as eMerge. We do not anticipate any material revenue from these enhancements and initiatives during 2004. Research and development expenses were $850,000, $1,681,000 and $1,662,000 in 2003, 2002 and 2001, respectively. The decrease in our research and development expenses during 2003 was largely a result of the staff reductions and other payroll

cost savings that were initiated at the end of 2002.

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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. The market for EDC in general and for our services specifically, has been an emerging one. Our marketing efforts have included selective participation in scientific and medical meetings to promote our services and we have occasionally used direct mail and journal advertisements to build awareness of our capabilities.

Because of the limited success of our marketing efforts, our focus has been direct contact with potential customers and maintaining a high retention and satisfaction rate with current customers. With these goals in mind, during 2003, we hired an individual to fill the newly-created position of Vice President and Global Head of Marketing and Sales. This new position along with our sales and account management staff will be focused on expanding our customer base and earning repeat business from our current customers.

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

It is our belief that DATATRAK EDC® can be competitive in this emerging marketplace. Our product has been tested and verified to be in compliance with FDA and other regulations. DATATRAK EDC® is delivered primarily via the Internet and supports multiple languages. Furthermore, many clinical trial sponsors have published statistics indicating that EDC can reduce the length of time to complete a clinical trial, and can reduce the number of questions concerning the clinical trial data thereby improving the quality of the clinical trial data.

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 percentage of revenue generated from customers who accounted for more than 10% of our revenue and the percentage of revenue generated by all other customers during 2003, 2002 and 2001.

	Year ended December 31,		
Customer	**2003**	**2002**	**2001**
Aventis Pharmaceuticals	22%	29%	22%
Control Delivery Systems	11%	20%	23%
CV Therapeutics			21%
Quintiles		*	11%
Daiichi Pharmaceutical	*	10%	*
Otsuka Research Institute	20%		
All other customers	39%	39%	21%

* Less than 10% of revenue.

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Contracting and Backlog

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

In some instances, we offer volume discounts to customers over multiple contracts. We estimate the volume discounts to be earned over the life the contracts to which the discount applies. As contracts progress, revenue is recorded using rates that reflect the anticipated volume discount to be achieved by the customer. The termination of a contract subject to a volume discount could result in a material adjustment to revenue previously recognized, in order to reflect the true economic value of the contract at the time of cancellation. To date, we have not recorded any revenue at rates that anticipate the earning of volume discounts by a customer.

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, 2003, our backlog was $14,600,000 compared to backlog of $12,616,000 at December 31, 2002. We expect to convert approximately $7,800,000 of our December 31, 2003 backlog into revenue during 2004. Our contracts can be cancelled or delayed at anytime and, therefore, our backlog, at any point in time, is not an accurate predictor of future levels of revenue.

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.

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

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develop products that are superior to or that otherwise achieve greater market acceptance than DATATRAK EDC®. In addition, we believe that certain large companies in the information technology industry may be forming alliances and attempting to capitalize on the data delivery options offered by the Internet. To the extent that our approach to EDC may gain market acceptance, larger companies in the information technology industry may develop competing technology to our detriment.

Regulatory Matters

The FDA has issued guidelines and rules on the use of computer systems in clinical trials relating to standard operating procedures, data entry, system design, security, system dependability and controls, personnel training, records inspection and certification of electronic signatures. Based on our review, we believe DATATRAK EDC® complies with these guidelines and rules. 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 are continuing to monitor the FDA s guidance to ensure compliance.

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

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, applies to health care providers, health plans and health care clearinghouses, or covered entities. Under HIPPA, covered entities are required to protect the confidentiality, integrity and availability of certain electronic patient information they collect, maintain, use, or transmit. Neither we, nor our customers, are covered entities under HIPPA, however we have taken steps, including encryption techniques, to ensure the confidentiality of all electronic patient information that is captured and transmitted through the use of DATATRAK EDC®.

Potential Liability and Insurance

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

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

Intellectual Property

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

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services in the market. We sell our services and license our software subject to contract provisions intended to provide appropriate protection to these valuable intellectual property assets.

Employees

As of February 29, 2004, we had approximately 65 full-time employees. None of our employees are represented by a union, and we consider relations with our employees to be satisfactory. We have employment agreements with all of our executive officers. Due to the early stage of development of our industry and business, the loss of the services of any of our executive officers could put us at a competitive disadvantage, since we would need to attract a qualified new executive to fill the vacancy. To address these risks, we must, among other things, continue to attract, retain and motivate qualified personnel.

Available Information

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

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 17,000 square feet of office space in Bonn, Germany for our European operations. We believe that our facilities are suitable and adequate for the current and anticipated conduct of our operations.

ITEM 3. LEGAL PROCEEDINGS

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

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

No matters were submitted to a vote of security holders during the fourth quarter of the fiscal year ended December 31, 2003.

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ITEM 4A. EXECUTIVE OFFICERS OF THE COMPANY*

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

Name	Age	Position
Dr. Jeffrey A. Green	48	President, Chief Executive Officer and Director
Terry C. Black	46	Vice President of Finance, Chief Financial Officer, Treasurer and Assistant Secretary
Marc J. Shlaes	47	Vice President of Research and Development
Dr. Wolfgang Summa	39	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.

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. 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 EDC industry for PadCom Clinical Research and Electronic Data Systems.

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PART II

ITEM 5. MARKET FOR REGISTRANT S COMMON SHARES AND RELATED SHAREHOLDER MATTERS

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

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 years ended December 31, 2003 and 2002, the high and low sale prices per common share, as reported by Nasdaq. These prices do not include retail markups, markdowns or commissions.

2003	High	Low
First Quarter	$1.76	$0.75
Second Quarter	$4.00	$1.16
Third Quarter	$6.20	$3.83
Fourth Quarter	$7.50	$3.97
2002	**High**	**Low**
First Quarter	$4.46	$2.30
Second Quarter	$3.70	$2.39
Third Quarter	$3.00	$1.50
Fourth Quarter	$2.00	$0.75

On February 29, 2004, the last sale price of our common shares as reported by Nasdaq was $7.76 per share. As of February 29, 2004, we had 83 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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ITEM 6. SELECTED FINANCIAL DATA

	Year Ended December 31,				
	2003	**2002**	**2001**	**2000**	**1999**
	(In thousands, except per share data)				
Statement of Operations Data:					
Revenue	$ 7,052	$ 4,721	$ 2,246	$ 1,994	$ 5,811
Direct costs	1,622	1,804	1,780	1,597	3,763
Gross profit	5,430	2,917	466	397	2,048
Selling, general and administrative expenses	5,551	7,893	7,210	5,726	5,871
Special items		364			
Depreciation and amortization	937	1,122	949	867	800
Loss from operations	(1,058)	(6,462)	(7,693)	(6,196)	(4,623)
Other income, net	14	71	339	912	14,727
(Loss) Income before income taxes	(1,044)	(6,391)	(7,354)	(5,284)	10,104
Income tax expense	4				384
Net (loss) income	$(1,048)	$(6,391)	$(7,354)	$(5,284)	$ 9,720
Net (loss) income per share: basic	$ (0.19)	$ (1.22)	$ (2.23)	$ (1.61)	$ 1.87
Shares used in the computation of basic net (loss) income per share	5,565	5,237	3,291	3,290	5,209
Net (loss) income per share: diluted	$ (0.19)	$ (1.22)	$ (2.23)	$ (1.61)	$ 1.84
Shares used in the computation of diluted net (loss) income per share	5,565	5,237	3,291	3,290	5,293

	December 31,

	2003	2002	2001	2000	1999
	(In thousands, except per share data)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 4,261	$ 2,244	$ 4,912	$ 12,040	$ 17,536
Working capital	3,468	1,380	4,129	11,645	16,983
Total assets	6,377	5,306	7,634	14,486	19,483
Long-term liabilities		24	162		
Accumulated deficit	(31,781)	(30,732)	(24,341)	(16,987)	(11,703)
Total shareholders equity	4,601	3,231	5,755	13,104	18,306
Book value per common share	$ 0.77	$ 0.61	$ 1.75	$ 3.98	$ 5.56
Cash dividends declared					

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 67% of our assets, or $4,261,000, 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 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 internet hardware known as DATATRAK EDC® to provide EDC and other services to clinical trial sponsors and CROs. Our future success is dependent on market acceptance of EDC in general, as an alternative to the traditional paper method of collecting clinical trial data, and acceptance of DATATRAK EDC® specifically. We may be unsuccessful in achieving commercial acceptance of the DATATRAK® process.

At December 31, 2003, our backlog was $14,600,000 compared to backlog of $12,616,000 at December 31, 2002. Our December 31, 2003 backlog consisted of 45 contracts with an average remaining value of $324,000. At December 31, 2002, our backlog consisted of 35 contracts with an average remaining value of $360,000. Our contracts in backlog at December 31, 2002 generated $4,193,000 of revenue during 2003. If we have no delays or cancellations to the contracts in backlog at December 31, 2003, we expect to convert approximately $7,800,000 of our December 31, 2003 backlog into revenue during 2004. Our contracts can be cancelled or delayed at anytime and, therefore, our backlog, at any point in time, is not an accurate predictor of future levels of revenue.

Critical Accounting Policies

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

Revenue Recognition

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

In some instances, we offer volume discounts to customers over multiple contracts. We estimate the volume discounts to be earned over the life the contracts to which the discount applies. As contracts progress, revenue is recorded using rates that reflect the anticipated volume discount to be achieved by the customer. The termination of a contract subject to a volume discount could result in a material adjustment to revenue previously recognized, in order to reflect the true economic value of the contract at the time of cancellation. To date, we have not recorded any revenue at rates that anticipate the earning of volume discounts by a customer.

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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 (SFAS) No. 86, Accounting for the Costs of Computer Software to be Sold, Leased, or Otherwise Marketed. Such costs are amortized over the lesser of three years or the economic life of the related product. 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 (APB) No. 25, Accounting for Stock Issued to Employees. Under APB No. 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 (FASB) SFAS No. 123, Accounting for Stock-Based Compensation requires use of option valuation models that were not developed for use in valuing employee stock options. On December 31, 2002, the FASB issued SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure. SFAS No. 148 amends SFAS No. 123, to provide alternative methods of transition to the fair value method of accounting for stock-based employee compensation. SFAS No. 148 does not amend SFAS 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 SFAS No. 123 or the intrinsic value method described in APB No. 25. We do not intend to adopt the fair value method of accounting and we have made the disclosures required by SFAS No. 148 in our consolidated financial statements.

Results of Operations

During 2002 and 2001 we recorded net operating losses of $6,462,000 and $7,693,000, respectively. During these years our operating expenses continued to increase from $9,939,000 in 2001 to $11,183,000, including special items of $364,000, in 2002. Our personnel costs, which have represented approximately 53.0% of our operating expenses, also increased from $5,180,000 in 2001 to $5,993,000 in 2002. We had approximately 80 and 60 employees at December 31, 2001 and 2002, respectively. During the second half of 2002, we took steps to reduce our annual operating costs, primarily through reductions in personnel costs. These cost cutting measures enabled us to reduce our personnel costs to $4,299,000 and our total operating expenses to $8,110,000 during 2003. At December 31, 2003 we had approximately 65 employees.

Our revenue growth has been hampered by the slow growth of the EDC market. However, our revenue has continued to grow from $2,246,000 in 2001 to $4,721,000 in 2002 and to $7,052,000 in 2003. This continued growth in revenue together with the decrease in our operating expenses allowed us to reduce our net operating loss to $1,058,000 in 2003.

At our estimated levels of revenue, projected operating costs and conversion of backlog into revenue, we anticipate that we will reach profitability during 2004, and record income from operations for the year ended December 31, 2004. In order to grow the business, and consistent with our anticipated growth in revenue, we anticipate that we will have approximately 85 employees at December 31, 2004.

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

	Year Ended December 31,		
	2003	**2002**	**2001**
Revenue	100.0%	100.0%	100.0%
Direct costs	23.0	38.2	79.3
Gross profit	77.0	61.8	20.7
Selling, general and administrative expenses	78.7	167.2	321.0
Special items		7.7	
Depreciation and amortization	13.3	23.8	42.3
Loss from operations	(15.0)	(136.9)	(342.6)
Other income, net	0.2	1.5	15.1
Net loss before income taxes	(14.8)	(135.4)	(327.5)
Income tax expense	0.1		
Net loss	(14.9)	(135.4)	(327.5)

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

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

Direct costs of revenue, mainly personnel costs, were $1,622,000 and $1,804,000 during the years ended December 31, 2003 and 2002, respectively. Our gross profit was $5,430,000 and $2,917,000 during 2003 and 2002, respectively. Personnel costs decreased by $132,000 during 2003 due to the cost cutting measures implemented at the end of 2002. Also during 2003 our internet service provider costs decreased by $107,000 due to decreasing rates. These decreases were offset by a $57,000 increase in other direct costs. These other direct costs are mainly travel expenses and other costs, which are billed to our customers. The $182,000 decrease in direct costs combined with our increased revenue resulted in a gross margin of 77.0% in 2003 compared to 61.8% in 2002. Based on our anticipated levels of revenue and our expected cost structure, we anticipate that our gross margin in 2004 will approximate the levels achieved in 2003.

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 decreased by 29.7% to $5,551,000 from $7,893,000 for the years ended December 31, 2003 and 2002, respectively. Staff reductions and other payroll cost savings caused personnel costs to decrease by $1,562,000 during the year ended December 31, 2003. Cost reductions in other areas resulted in additional savings of $780,000 during the year ended December 31, 2003. The decrease in SG&A expenses is consistent with what we anticipated when staff reductions and other cost-cutting measures were implemented at the end of 2002. We anticipate approximately a 30% increase in 2004 compared to 2003 as a result of increased personnel and growth of the business.

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

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

During 2003, we had federal alternative minimum tax of $4,000 due to income earned by our U.S. based operations. Due to our consolidated net loss and our net operating loss carryforwards, we had no other federal, state or local income tax expense in 2003. At December 31, 2003 we had a net operating loss carryforward of approximately $20,920,000, for United States income tax purposes, which will expire through the year 2022. We also had a net operating loss carryforward of approximately 8,503,000 Euro for German income tax purposes with no expiration date. Due to the uncertainty of the recoverability of our deferred tax assets, we have fully provided for our deferred tax assets through a valuation allowance.

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

Revenue for the year ended December 31, 2002 increased by 110.2% to $4,721,000, compared to $2,246,000 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 $1,804,000 and $1,780,000 during the years ended December 31, 2002 and 2001, respectively. Our gross profit was $2,917,000 and $466,000 during 2002 and 2001, respectively. A $69,000 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 61.8% in 2002 compared to 20.7% in 2001.

SG&A expenses increased by 9.5% to $7,893,000 from $7,210,000 for the years ended December 31, 2002 and 2001, respectively. The increase was primarily due to increased personnel costs of $744,000 caused by an increase in expenses related to sales and marketing, software development and corporate office personnel.

During 2002, we recorded special charges of $364,000. Included in special items is $126,000 of expenses associated with our proposed acquisition of Oriam, SA, from which we withdrew in January 2003. Also, during 2002, $238,000 of expenses related to the reduction of 20 employees were recorded.

Depreciation and amortization expense increased to $1,122,000 during the year ended December 31, 2002, from $949,000 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.

Other income for the year ended December 31, 2002 totaled $72,000, compared to $339,000 for the year ended December 31, 2001. Other income includes interest income, which decreased $293,000 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.

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 August 2003 we received $2,239,000 in net proceeds from the completion of a private placement of our common shares.

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Contracts with our customers usually require a portion of the contract amount to be paid at the time the contract is initiated. Additional payments are generally received monthly as work on the contract progresses. We record all amounts received as a liability (deferred revenue) until work has been completed and revenue is recognized. Cash receipts do not necessarily correspond to costs incurred or revenue recognized. We typically receive a low volume of large-dollar receipts. Our accounts receivable will fluctuate due to the timing and size of cash receipts. Our contracting and collection practices are designed to maintain an average collection period for accounts receivable of one to 3 months. Any increase in our normal collection period for accounts receivable could negatively impact our cash flow from operations and our working capital. At December 31, 2003, our average collection period for accounts receivable was 43 days compared to 53 days at December 31, 2002. Accounts receivable (net of allowance for doubtful accounts) was $788,000 at December 31, 2003 and $884,000 at December 31, 2002. Our increased revenue was offset by increased collections to allow the overall accounts receivable to decrease in 2003. Deferred revenue was $897,000 at December 31, 2003 compared to $902,000 at December 31, 2002.

Cash and cash equivalents increased $107,000 during the year ended December 31, 2003. This was the result of $125,000 and $1,942,000 used in operating and investing activities, respectively, offset by $2,173,000 provided by and financing activities and currency exchange rate fluctuations. Cash used for operating activities resulted from the funding of net operating losses and other working capital needs. Investing activities included net cash uses of $1,896,000 from purchases and maturities of short-term investments, $184,000 used to purchase property and equipment and a $138,000 decrease in our restricted cash balance. Financing activities included the $2,300,000 in cash received from our private placement of common shares and other equity transactions, and $138,000 used to repay a capital lease obligation.

At December 31, 2003, we had working capital of $3,468,000, and our cash, cash equivalents and short-term investments totaled $4,261,000. Our working capital has increased by $2,088,000 since December 31, 2002. The increase was primarily the result of the $2,017,000 increase in our cash, cash equivalents and short-term investments, due to our private placement of common shares. Changes in other current assets and liabilities caused working capital to increase by $71,000.

We are party to two separate lease agreements, which require us to maintain restricted cash balances. Our total restricted cash balance was $98,000 at December 31, 2003.

We intend to continue to fund the enhancement and testing of the DATATRAK EDC® software, as well as continue to invest in the development of the DATATRAK® process. Our operations and the EDC market are still in a developmental stage. We have experienced revenue growth; and anticipate positive cash flow from operations during 2004 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 $825,000 for the twelve months ending December 31, 2004, for the continued commercialization and enhancement of DATATRAK EDC®. Of the $825,000 total, $254,000 is required to upgrade current systems. The remaining $571,000 is in conjunction with the anticipated growth of our business, and is to some extent discretionary. Additionally, we anticipate spending $354,000 for maintenance of our information technology infrastructure during 2004. We expect to fund these working capital requirements, 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 for the foreseeable future. However, we may need to raise additional funds to offset delays or cancellations of contacts, support expansion, respond to competitive pressures, acquire complementary businesses or technology or take advantage of unanticipated opportunities. We may raise additional funds by selling debt or equity securities, by entering into strategic relationships or through other arrangements. Additional capital may not be available on acceptable terms, if at all. To the extent that additional equity capital is raised, it could have a dilutive effect on our existing shareholders.

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Contractual Obligations

The table below shows our contractual cash obligations, expressed in thousands, at December 31, 2003.

	Payments Due by Period				
Contractual Obligations	**Total**	**Less than 1 year**	**1 3 years**	**4 5 years**	**After 5 years**
Capital lease obligations	$ 24	$ 24	$	$	$
Operating leases	3,949	551	1,126	1,060	1,212
Total contractual cash obligations	$3,973	$ 575	$1,126	$1,060	$1,212

Inflation

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

Interest Rate Risk

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

Foreign Currency Risk

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

Our financial position and results of operations are impacted by translation adjustments caused by the conversion of foreign currency accounts and operating results into U.S. dollars for financial reporting purposes. During 2003 the average exchange rate between the Euro and the U.S. dollar by increased by approximately 19%. The conversion of our foreign operations into U.S. dollars upon consolidation resulted in a net loss that was approximately $250,000 higher than would have been recorded had the exchange rate between the Euro and the U.S. dollar remained constant throughout 2003.

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.

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

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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 cau