DATATRAK INTERNATIONAL INC
Form 10-K
March 11, 2005

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

FORM 10-K

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

(Mark One) **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
þ
For the fiscal year ended December 31, 2004

OR

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

Commission file number 000-20699

DATATRAK International, Inc.

(Exact name of registrant as specified in its charter)

Ohio	34-1685364
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer identification no.)
6150 Parkland Boulevard, Mayfield Hts., Ohio	44124
(Address of principal executive offices)	(Zip code)

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

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

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

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

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. þ

Indicate by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2).
Yes o No þ

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

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

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PART I

ITEM 1. BUSINESS

General

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

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

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

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

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

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

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

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

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

Overview of the Clinical Research Industry

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

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

DATATRAK Software and Services

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

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

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

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

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

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

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

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

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

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

Customers and Marketing

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

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

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

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

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

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

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

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

* Less than 10% of revenue.

Contracting and Backlog

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

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

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

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Competition

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

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

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

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

Regulatory Matters

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

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

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

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

Potential Liability and Insurance

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

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

Intellectual Property

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

Employees

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

Available Information

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

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

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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 any current such litigation will have a material adverse effect on its results of operations or financial condition.

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

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

PART II

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

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

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

2004	High	Low
First Quarter	$ 10.16	$ 6.09
Second Quarter	$ 13.22	$ 9.08
Third Quarter	$ 13.22	$ 9.20
Fourth Quarter	$ 12.30	$ 9.80

2003	High	Low
First Quarter	$ 1.76	$ 0.75
Second Quarter	$ 4.00	$ 1.16
Third Quarter	$ 6.20	$ 3.83
Fourth Quarter	$ 7.50	$ 3.97

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

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

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ITEM 6. SELECTED FINANCIAL DATA

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

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

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

General

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

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

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

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

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

Critical Accounting Policies

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

Revenue Recognition

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

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

Software Development Costs

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

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

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

Stock Based Compensation

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

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

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

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

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

Recently Issued Accounting Standards

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

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

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

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

Results of Operations

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SG&A expenses include all administrative personnel costs, business and software development costs, and all other expenses not directly chargeable to a specific contract. These expenses decreased by 29.7% to $5,551,000 from $7,893,000 for the years ended December 31, 2003 and 2002, respectively. Staff reductions and other payroll cost savings caused personnel costs to decrease by $1,562,000 during the year ended D