DATATRAK INTERNATIONAL INC
Form 10-K
March 13, 2006

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)

þ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2005

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.
Series A Junior Participating Preferred Stock Purchase Rights.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes o No þ
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) the Act.
Yeso No þ
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. o
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer (as defined in Exchange Act Rule 12b-2).
Large accelerated filer o Accelerated filer þ Non-accelerated filer o

Indicate by check mark whether the registrant is a shell company (as defined in Exchange Act Rule 12b-2).

Yes o No þ

As of June 30, 2005, the aggregate market value of the 9,460,731 common shares then outstanding, which together constituted all of the voting shares of the registrant, held by non-affiliates was $109,271,443 (based upon the closing price of $11.55 per common share on the Nasdaq SmallCap Market on June 30, 2005). 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, 2006, the registrant had 11,355,246 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, 2005.

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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 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 establishing the market presence necessary to compete in the evolving EDC sector of the clinical research industry.

In December 2004, we entered into an alliance agreement with SAS Institute Inc. (SAS). Pursuant to this alliance, DATATRAK and SAS are making 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 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, who 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.

On February 13, 2006, we acquired all of the outstanding stock of ClickFind, Inc. (ClickFind), a company focused on the application of technology in clinical trials, located in Bryan, Texas, for a total purchase price of $18,000,000, less approximately $328,000 in certain transaction expenses and certain outstanding indebtedness of ClickFind. The purchase price consisted of approximately $4,000,000 of cash, $4,000,000 in notes payable and approximately $10,000,000 in Common Shares (1,026,522 Common Shares). ClickFind s product suite will now be known as DATATRAK eClinical . As a result of the acquisition, we expect to have the most extensive eClinical software suite in the clinical trials industry.

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 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. Automating data entry and review procedures can save time in the drug development and medical device approval process, and possibly result in enhanced patient safety. 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 50 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 more timely and 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 non-interventional 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 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 an EDC certification program known as eMerge. Research and development expenses were $1,650,000, $1,142,000, and $850,000 in 2005, 2004, and 2003, respectively. The low level of 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 and 2005, in conjunction with our increased revenue, we increased expenses in research and development.

During the performance of clinical trials, a variety of technology applications are used for the collection, management and storage of information. Many of these applications perform limited but important functions that contribute to the overall successful accomplishment of a clinical trial. Because the use of technology in this industry is relatively new, as compared to others, the specific functionalities of individual technology applications have advanced as single point solutions rather than an overall product suite, existing under a single application, architecture and corporate offering. As the global clinical trial market transitions from a paper-based data collection and management process to a technology-enabled process over the next several years, we believe that the clinical trials industry will increasingly demand multiple applications. As the demand for multiple applications increase, we believe sponsors of clinical research will gravitate from the challenges encountered with information collected and residing in several disparate applications to one that houses multiple applications under a single software architecture and corporate structure. This would represent a simplified approach from the workflow process of clinical trials itself and would also yield contracting advantages by being able to deal with only one vendor for a variety of necessary software applications.

Our recent ClickFind acquisition will expand our product offerings. This new product, DATATRAK eClinical , will provide the following capabilities: EDC, interactive voice response systems (IVRS) (via phone or internet), medical coding, a randomization tool, clinical trial management system (CTMS), drug inventory management, digitized electrocardiograms, imaging capabilities, electronic patient recorded outcomes (ePRO) and workgroup collaboration capabilities. Several of these new capabilities will represent new revenue opportunities for us as the DATATRAK eClinical offering matures. DATATRAK eClinical has been used in many clinical trails in nineteen separate countries but has never been utilized in a large multi-national clinical trial with over 1,000 patients, and will require additional investment and testing on our part before it can be used in a clinical trial involving such large volumes of information.

All clinical trials currently being performed with DATATRAK EDC® will continue through conclusion with that product suite. At this time, it is anticipated that the DATATRAK EDC® platform will be utilized in these, and perhaps some new, clinical trials until the end of 2009. As such, we will provide two different architectures for the use of technology in clinical trials until current trials, and perhaps future trials, using the previous platform are finished. We will continue to support and provide, as needed, appropriate service packs for the maintenance of DATATRAK EDC® as well as DATATRAK eClinical . However, no extensive, future development efforts are planned for DATATRAK EDC®, and following the conclusion of all clinical trials using DATATRAK EDC®, that product suite will be discontinued.

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 our software with SAS® Drug Development software to allow clinical trial sponsors to have immediately analyzable SAS datasets, automatically updated, for their clinical trials.

Our 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 2006.

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.

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 our software offering can be competitive in this emerging marketplace. Our product has been tested and verified to be in compliance with FDA and other regulations. Our software offering 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.

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® and DATATRAK eClinical software offerings 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 2005, 2004 and 2003.

	Year ended December 31,		
Customer	**2005**	**2004**	**2003**
Aventis Pharmaceuticals	*	15%	22%
Control Delivery Systems	*	*	11%
Otsuka Research Institute	59%	55%	20%

* Less than 10% of revenue.

Contracting and Backlog

Our contracts provide a fixed price for each component or service to be delivered, and revenue is recognized as these components or services are delivered. We recognize revenue based on the performance or delivery of the following specified services or components of its EDC contracts in the manner described below:

Project management and data management (design, report and export) services are recorded as revenue proportionally over the life of a contract as services are performed based on the contractual billing rate per hour for those services.

Data items revenue is earned based on a price per data unit as data items are entered into DATATRAK s hosting facility.

Classroom training services revenue is recognized as classroom training is completed, at rates based on the length of the training program.

Internet-based training services revenue is recognized on a per user basis as self-study courses are completed.

Help desk revenue is recognized based on a monthly price per registered user under the contract.

Services provided by us that are in addition to those provided for in our contracts are billed on a fee for service basis as services are completed. Costs associated with contract revenue are recognized as incurred. Costs that are paid directly by our clients, 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. 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 a contract progresses, revenues are 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 years ended December 31, 2005 and December 31, 2004, we deferred $56,000 and $69,000 of revenue, respectively, as a result of contracts subject to volume discounts. No revenue was deferred in 2003 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, 2005, our backlog was $20,324,000 compared to backlog of $14,057,000 at December 31, 2004. We expect to convert approximately $11,200,000 of our December 31, 2005 backlog into revenue during 2006. 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. As a result of our transactional and service-based business model combined with the dynamic nature of the clinical trials market where changes in scope are common, backlog has historically been an imprecise predictor of short-term 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. 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 our software 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. Because of the expanded software offering obtained through the acquisition of ClickFind, we now have additional competitors that we did not have before this transaction. The DATATRAK eClinical software suite has a variety of unified offerings, such as core laboratory ECG and imaging capabilities; IVRS both voice- and web-activated; CTMS; Randomization, Medical Coding and ePRO. Each of these individual offerings have distinct single point solution competitors in the clinical trial market. Sponsors of clinical research have a variety of choices in which to satisfy each of these capabilities for their clinical trials from many different organizations. We are not aware of any competitors that have all of these individual components contained under one software offering.

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. Clinical trial sponsors also may continue to contract with individual vendors instead of utilizing our single software solution.

We are aware of other EDC systems that compete or, in the future, may compete directly with DATATRAK EDC® and DATATRAK eClinical . 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® and DATATRAK eClinical . Either existing or new competitors may also develop products that are superior to or that otherwise achieve greater market acceptance than our software. 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 that both DATATRAK EDC® and DATATRAK eClinical comply 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. Any release of FDA guidance that is significantly inconsistent with the design of our software 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 (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 our software.

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®, DATATRAK eClinical 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 an errors and omissions professional liability insurance

policy to cover claims in an amount up to $5,000,000 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® and DATATRAK eClinical 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, 2006, we had approximately 110 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 which includes 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 or 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.

ITEM 1A. RISK FACTORS

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 performance expressed or implied by the forward-looking statements. We have identified the following important factors, which could cause our actual operational or financial results to differ materially from any projections, estimates, forecasts or other forward-looking statements made by or on our behalf. Under no circumstances should the factors listed below be construed as an exhaustive list of all factors that could cause actual results to differ materially from those expressed in forward-looking statements. We undertake no obligation to review or confirm analysts expectations or estimates or to release publicly any revisions to

forward-looking statements contained herein to take into account events or circumstances that occur after the date of this Annual Report on Form 10-K. In addition, we do not undertake any responsibility to update publicly the occurrence of unanticipated events, which may cause actual results to differ from those expressed or implied by the forward-looking statements contained herein.

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

We began providing EDC services in 1997 and have a limited operating history upon which our performance may be evaluated. Although we were profitable in 2004 and 2005, we had previously recognized operating losses in each year since 1997. Our cumulative operating loss since 1997 from EDC operations totaled $37,411,000 at December 31, 2005. We anticipate that we will be profitable in 2006. However, any number of factors, including, but not limited to, termination or delays in contracts, inability to grow and convert backlog into revenue or being unable to quickly reduce costs if required, could cause us to record losses in 2006 and in future periods.

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

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

Our quarterly results fluctuate significantly.

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

our success in obtaining new contracts,

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

the timing of clinical trial sponsor decisions to conduct new clinical trials or cancel or delay ongoing trials.

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

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

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

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

Although our contracts provide that we are entitled to receive revenue earned through the date of termination, our customers generally are free to delay or terminate a clinical trial or our contract related to

the trial at any time. The length of a typical clinical trial contract varies from several months to several years. Clinical trial sponsors may delay or terminate clinical trials for several reasons, including

unexpected results or adverse patient reactions to a potential product,

inadequate patient enrollment or investigator recruitment,

manufacturing problems resulting in shortages of a potential product, or

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

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

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

Our primary customers are companies in the pharmaceutical industry. Our business is substantially dependent on the research and development expenditures of companies in this industry. The extent to which we rely on revenue from one customer varies from period to period, depending upon, among other things, our ability to generate new business 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. During 2005, one customer accounted for 59% of our total revenue for the year. Our operations could be materially and adversely affected by, among other things,

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

any decrease in these industries research and development expenditures, or

changes in the regulatory environment in which companies in these industries operate.

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

Demand for our services is largely a function of the regulatory requirements associated with the approval of a New Drug Application by the FDA. These requirements are more stringent and thus more burdensome than those imposed by many other developed countries. In recent years, efforts have been made to streamline the drug approval process and coordinate U.S. standards with those of other developed countries. Changes in the level of regulation, including a relaxation in regulatory requirements or the introduction of simplified drug approval procedures could reduce the demand for our services. Several competing proposals to reform the system of health care delivery in the United States have been considered by Congress from time to time. To date, none of these proposals have been adopted.

The FDA s guidelines and rules related to the use of computerized systems in clinical trials are still in the early stages of development. Our software 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® or DATATRAK eClinical may cause us to incur substantial costs to remain in compliance with FDA guidance and regulations.

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

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

EDC software vendors,

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

vendors offering single component solutions and

in-house development efforts within large pharmaceutical companies.

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

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

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

Our competitive position and business may be adversely affected if we are unable to protect our intellectual property rights or infringe upon the intellectual property rights of others.

Intellectual property rights, including patent rights, are significant to our ongoing operations and future opportunities. Our success will depend, in part, on our ability to secure our own intellectual property rights (*e.g.*, patents, copyrights, trademarks, trade secrets), obtain licenses to technology owned by third parties when necessary, and conduct our business without infringing on the proprietary rights of others. There can be no assurance, however, that our proprietary rights will provide us significant protection or commercial advantage or that measures taken to protect our confidential information will adequately prevent the disclosure or misuse of such confidential information. In addition, there can be no assurance that, in the future, a third party will not assert that we are violating their proprietary rights, including that our technologies, products or services infringe their patents. In that event, we could incur substantial costs and diversion of the time and attention of management and technical personnel in defending ourselves against any such claims. Any meritorious claim of intellectual property infringement against us could have a material adverse effect on our competitive position and business.

We may not be able to successfully integrate our recently acquired business into our current business operations.

We recently completed an acquisition of ClickFind and its product suite. This new product suite, now called DATATRAK eClinical , will play a significant role in our efforts to continue to be a leading ASP for the EDC industry. We may not be able to successfully integrate and profitably manage ClickFind and our new software offering without substantial costs, delays or other problems. Acquisitions also may involve a number of special risks, including adverse short-term effects on our reported operating results, potentially dilutive issuances of equity securities, the incurrence of debt and contingent liabilities, diversion of management s attention, dependence on retention hiring and training of key personnel and risks associated with unanticipated problems or legal liabilities some or all of which could have a material adverse effect on our business, results of operations and financial condition.

We will incur increased costs associated with the integration of our new product suite.

All clinical trials currently being performed with DATATRAK EDC® will continue through conclusion with that product suite. At this time, it is anticipated that the DATATRAK EDC® platform will be utilized in these, and perhaps some new, clinical trials until the end of 2009. As such, we will provide two different architectures for the use of technology in clinical trials until current trials, and perhaps future trials, using the previous platform are finished. We will incur additional costs by continuing to support and provide, as needed, appropriate service packs for the maintenance of DATATRAK EDC® as well as supporting and providing appropriate service packs for the maintenance of DATATRAK eClinical . We will also incur additional costs to integrate the DATATRAK eClinical product into our current operating systems.

Furthermore, our two product offerings will run on parallel systems, as such we will incur additional costs of maintaining two parallel production systems.

DATATRAK eClinical , which has been used in many clinical trails in nineteen separate countries, has never been utilized in a large multi-national clinical trial with over 1,000 patients. As such, we are investing in additional infrastructure, so that DATATRAK eClinical can be scaled to meet the needs of clinical trials with such large volumes of data and the software performs to the level of satisfaction that our customers have come to expect. We may incur unforeseen costs if significant modification and testing become necessary to ensure the scalability of DATATRAK eClinical .

The price of our common shares could be adversely affected by the dilution caused by the common shares issued in our recently completed acquisition.

In February 2006, we issued 1,026,522 of our unregistered common shares to the former shareholders of ClickFind as part of the acquisition of the outstanding stock of ClickFind. These 1,026,522 common shares represent approximately 9.0% of our outstanding common shares, as of February 28, 2006. Sales of a substantial number of these common shares in the public market could depress the market price of our common shares. The perceived risk resulting from the sale of these common shares could cause some of our shareholders to sell their common shares, thus causing the price of our common shares to further decline. In addition, the downward pressure on the price of our common shares could cause some of our shareholders to engage in short sales of our common shares, which may cause the price of our common shares to decline even further.

We have Anti-takeover Provisions and Preferred Share Purchase Rights

Our Articles of Incorporation and By-Laws contain provisions that may discourage a third party from acquiring, or attempting to acquire us. These provisions could limit the price that certain investors might be willing to pay for our common shares. In addition preferred shares of our stock can be issued by our Board of Directors, without shareholder approval, whether under our shareholder rights plan or for other uses determined by the Board. The issuance of preferred shares may adversely affect the rights of common shareholders, the market price of our common shares and may make it more difficult for a third party to acquire a majority of our outstanding common shares. At the present time, we do not plan to issue any preferred shares.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We presently lease approximately 13,000 square feet of office space in Mayfield Heights, Ohio. This space is used for our executive offices and U.S. operations. In addition, we have U.S. based operations in Bryan, Texas, where we lease approximately 6,000 square feet of office space. 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, we are 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 our 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, 2005.

ITEM 4A. EXECUTIVE OFFICERS OF THE COMPANY*

The name, age and positions of each of the Company s executive officers, as of February 28, 2006, are as follows:

Name	Age	Position
Dr. Jeffrey A. Green	50	President, Chief Executive Officer and Director
Terry C. Black	48	Vice President of Finance, Chief Financial Officer, Treasurer and Assistant Secretary
Marc J. Shlaes	51	Vice President of Product Strategy
Dr. Wolfgang Summa	41	Vice President of Global Operations
Jim Bob Ward	45	Vice President of eClinical Development

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

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

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

Marc J. Shlaes, BB. Mr. Shlaes has served as our Vice President of Product Strategy since February 2006. Mr. Shlaes is responsible for the continuing innovation of our product solutions. From December 2000 through January 2006, Mr. Shlaes served as our Vice President of Research and Development. Mr. Shlaes has been employed by us since 1998. Prior to joining us, Mr. Shlaes served in a variety of positions in the software development and delivery industry.

Wolfgang Summa, PhD., MSc. Dr. Summa has served as our Vice President of Global Operations since December 2000. Dr. Summa is responsible for our operational strategy including delivery of our software to customers. Dr. Summa has been employed by us since 1998. Prior to joining us, Dr. Summa served in various research positions within the EDC industry.

Jim Bob Ward MS. Mr. Ward has been our Vice President of eClinical Development since February 2006. Mr. Ward is responsible for the continuing development of our DATATRAK eClinical product suite. Mr. Ward is the former President and Chief Executive Officer of ClickFind. From 2000 through January 2005, while employed at ClickFind, Mr. Ward developed the workflow and clinical research applications that make up the DATATRAK eClinical product suite.

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 stock split adjusted price of $9.00 per share and commenced trading on Nasdaq on that date. On July 20, 2005, our Board of Directors approved a three-for-two share split that was distributed in the form of a 50% share dividend. Our shareholders of record at the close of business on August 15, 2005 received one additional Common Share for every two common shares held on that date. The new common shares were distributed on or around August 31, 2005 and began trading ex-dividend on September 1, 2005. We have restated all prior reported common share and per share amounts as if the share split had occurred at the beginning of the earliest period being reported. The following table sets forth, for the years ended December 31, 2005 and 2004, the high and low sale prices per common share, as reported by Nasdaq. These prices do not include retail markups, markdowns or commissions.

2005	High	Low
First Quarter	$14.47	$6.97
Second Quarter	$12.99	$9.33
Third Quarter	$16.00	$8.43
Fourth Quarter	$12.74	$8.48

2004	High	Low
First Quarter	$6.77	$4.06
Second Quarter	$8.81	$6.05
Third Quarter	$8.81	$6.13
Fourth Quarter	$8.20	$6.53

On February 28, 2006, the last sale price of our common shares as reported by Nasdaq was $7.50 per share. As of February 28, 2006, we had 86 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.

ITEM 6. SELECTED FINANCIAL DATA

	Year Ended December 31,				
	2005	2004	2003	2002	2001
	(In thousands, except per share data)				
Statement of Operations Data:					
Revenue	$ 15,735	$ 11,305	$ 7,052	$ 4,721	$ 2,246
Direct costs	3,789	2,634	1,622	1,804	1,780
Gross profit	11,946	8,671	5,430	2,917	466
Selling, general and administrative expenses	10,025	7,229	5,551	7,893	7,210
Special items				364	
Depreciation and amortization	748	651	937	1,122	949
Income (loss) from operations	1,173	791	(1,058)	(6,462)	(7,693)
Other income, net	182	35	14	71	339
Income (loss) before income taxes	1,355	826	(1,044)	(6,391)	(7,354)
Income tax (benefit) expense	(1,183)	9	4		
Net income (loss)	$ 2,538	$ 817	$ (1,048)	$ (6,391)	$ (7,354)
Net income (loss) per share: basic	$ 0.25	$ 0.09	$ (0.13)	$ (0.81)	$ (1.49)
Shares used in the computation of basic net income (loss) per share	10,204	9,149	8,348	7,856	4,936
Net income (loss) per share: diluted	$ 0.22	$ 0.08	$ (0.13)	$ (0.81)	$ (1.49)
Shares used in the computation of diluted net income (loss) per share	11,386	10,237	8,348	7,856	4,936

	December 31,				
	2005	2004	2003	2002	2001
	(In thousands, except per share data)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	$ 9,363	$ 7,919	$ 4,261	$ 2,244	$ 4,912
Working capital	10,796	8,575	3,468	1,380	4,129
Total assets	16,107	11,941	6,377	5,306	7,634
Long-term liabilities				24	162
Accumulated deficit	(28,425)	(30,964)	(31,781)	(30,732)	(24,341)
Total shareholders equity	13,697	10,117	4,601	3,231	5,755
Book value per common share	$ 1.33	$ 1.02	$ 0.51	$ 0.41	$ 1.17
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.

Approximately 58% of our assets, or $9,363,000, is held in cash, cash equivalents and short-term investments. During 2005 and 2004, we recorded operating income for the first time since commencing EDC operations in 1997. 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 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 our DATRAK EDC® and DATATRAK eClinical software products specifically.

At December 31, 2005, our backlog was $20,324,000 compared to backlog of $14,057,000 at December 31, 2004. Our December 31, 2005 backlog consisted of 69 contracts with an average remaining value of $295,000. At December 31, 2004, our backlog consisted of 58 contracts with an average remaining value of $242,000. Our contracts in backlog at December 31, 2004 generated $13,513,000 of revenue during 2005. If we have no delays or cancellations to the contracts in backlog at December 31, 2005, we expect to convert approximately $11,200,000 of our December 31, 2005 backlog into revenue during 2006. 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. As a result of our transactional and service-based business model combined with the dynamic nature of the clinical trials market where changes in scope are common, backlog has historically been an imprecise predictor of short-term 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 contracts provide a fixed price for each component or service to be delivered, and revenue is recognized as these components or services are delivered. We recognize revenue based on the performance or delivery of the following specified services or components of our EDC contracts in the manner described below:

Project management and data management (design, report and export) services are recorded as revenue proportionally over the life of a contract as services are performed, based on the contractual billing rate per hour for those services.

Data items revenue is earned based on a price per data unit as data items are entered into our hosting facility.

Classroom training services revenue is recognized as classroom training is completed, at rates based on the length of the training program.

Internet-based training services revenue is recognized on a per user basis as self-study courses are completed.

Help desk revenue is recognized based on a monthly price per registered user under the contract.

Services provided by us that are in addition to those provided for in our contracts are billed on a fee for service basis as services are completed. Costs associated with contract revenue are recognized as incurred. Costs that are paid directly by our clients, 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 a contract progresses, revenues are 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 years ended December 31, 2005 and December 31, 2004, we deferred $56,000 and $69,000 of revenue, respectively, as a result of our contracts subject to volume discounts. No revenue was deferred in 2003 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 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. 148, Accounting for Stock-Based Compensation Transition and Disclosure, requires disclosure of compensation expense under both APB No. 25 and SFAS No. 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		
	2005	**2004**	**2003**
Weighted average risk free interest rate	4.2%	4.1%	4.3%
Weighted average volatility of the expected market price of the common shares	1.01	1.01	1.15
Dividend yield	0.0%	0.0%	0.0%
Weighted-average expected life of the option	7 years	8 years	7 years
Weighted-average fair value per share of options granted	$9.90	$6.68	$2.58

For purposes of pro forma disclosures, the estimated value of the options is amortized to expense over the options vesting period.

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

	Year Ended December 31,		
	2005	2004	2003
Net income (loss) recorded	$ 2,538,000	$ 817,000	$ (1,049,000)
Plus: stock compensation expense recognized	66,000	40,000	68,000
Less: stock compensation expense that would have been recognized under SFAS No. 123	894,000	736,000	634,000
Pro forma net income (loss)	$ 1,710,000	$ 121,000	$ (1,615,000)
Pro forma basic income (loss) per share	$ 0.17	$ 0.01	$ (0.19)
Pro forma diluted income (loss) per share	$ 0.15	$ 0.01	$ (0.19)

On December 16, 2004, the FASB issued SFAS No. 123(Revised 2004), Share-Based Payment, which is a revision of SFAS No.123, Accounting for Stock-Based Compensation. SFAS No. 123(R) supersedes APB No. 25, and amends SFAS No. 95, Statement of Cash Flows. Generally, the approach in SFAS No. 123(R) is similar to the approach described in SFAS No. 123. However, SFAS No. 123(R) requires all share based payments to employees, including grants of employee stock options, to be recognized in the income statement based on their fair values. Pro forma disclosure will no longer be an alternative. On April 14, 2005, the U.S. Securities and Exchange Commission (SEC) announced a deferral of the effective date of SFAS 123(R) for calendar year-end companies until January 1, 2006.

As permitted by SFAS No. 123, we currently account for share based payments to employees using APB No. 25, and as such, generally recognize no compensation cost for employee stock options. Accordingly, the adoption of SFAS 123(R) s fair value method may have a significant impact on our results of operations, although it will have no impact on our overall financial position. We will adopt SFAS No. 123(R) on January 1, 2006. We will adopt SFAS No. 123 using the modified prospective method in which compensation cost is recognized beginning January 1, 2006 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. We have chosen to use the Black-Scholes option valuation model in valuing stock options granted prior to January 1, 2006, and will continue to use this valuation model for options granted after the effective date of SFAS No. 123(R). The adoption of SFAS 123(R) will increase our operating expenses by approximately $1,250,000 in the aggregate over the four year period beginning in January 2006 through December 2009 for options that remain unvested as of January 1, 2006. During the year ending December 31, 2006, we expect to record approximately $500,000 of stock compensation expense, as a result of the adoption SFAS No. 123(R). 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, at this time we do not anticipate granting any additional stock options.

Income Taxes

The Company follows SFAS No. 109, Accounting for Income Taxes. This accounting standard requires that the liability method be used in accounting for income taxes. Under this accounting method, deferred tax assets and liabilities are determined based on the differences between the financial reporting basis and the tax basis of assets and liabilities and are measured using the enacted tax rates and laws that apply in the periods in which the deferred tax asset or liability is expected to be realized or settled. A valuation allowance is provided for deferred tax assets for which realization currently is not certain. Quarterly income taxes are recorded at the statutory rate, based on annual forecasted income.

The Company has substantial net operating loss carryforwards from prior years. Until 2005, the existence of operating losses provided sufficient negative evidence under SFAS No. 109, requiring a full valuation allowance against DATATRAK s deferred tax assets. This situation changed in 2005, as the

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Company realized taxable income of approximately $1,900,000 on a cumulative basis over the past three years. Given DATATRAK s ability to generate these profits, management now believes that a full valuation allowance on DATATRAK s deferred tax assets is no longer necessary. However, because the EDC market is still developing, it is difficult to predict taxable income very far into the future. Therefore, the reduction in the valuation allowance of $1,200,000 recorded in 2005 reflects estimates of the next three year s taxable income based on 2005 actual results, with adjustments for known changes and no assumptions for growth. The reduction in the deferred tax asset valuation allowance is based on historical results and should not be viewed as an estimate of future earnings.

Beginning in the first quarter of 2006, DATATRAK will record a tax provision at the statutory rate against quarterly pre-tax income. An evaluation will be made at each annual reporting period regarding the continuing need for a valuation allowance, and appropriate adjustments to the valuation allowance will be made at such time.

Results of Operations

Despite the slow growth of the EDC market, our revenue has grown from $7,052,000 in 2003 to $11,305,000 in 2004 and $15,735,000 in 2005. In conjunction with the growth in revenue, our operating expenses increased to $10,514,000 in 2004 and $14,562,000 in 2005. Personnel costs represented approximately 55.0%, or $5,813,000, of our operating costs during 2004 and approximately 49.0%, or 7,083,000, of our operating costs during 2005. We had approximately 80 employees at December 31, 2004 and approximately 90 employees at December 31, 2005. Our continued growth in revenue allowed us to record operating income in the amount of $791,000 and $1,173,000 for the years ended December 31, 2004 and December 31, 2005, 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 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 compared to $6,462,000 in 2002.

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,		
	2005	2004	2003
Revenue	100.0%	100.0%	100.0%
Direct costs	24.1	23.3	23.0
Gross profit	75.9	76.7	77.0
Selling, general and administrative expenses	63.7	63.9	78.7
Depreciation and amortization	4.8	5.8	13.3
Income (loss) from operations	7.4	7.0	(15.0)
Other income, net	1.2	0.3	0.2
Net income (loss) before income taxes	8.6	7.3	(14.8)
Income tax (benefit) expense	(7.5)	0.1	0.1
Net income (loss)	16.1	7.2	(14.9)

Year ended December 31, 2005 compared with year ended December 31, 2004

Revenue for the year ended December 31, 2005 increased by 39.2% to $15,735,000, compared to $11,305,000 for the year ended December 31, 2004. During the year ended December 31, 2005, we recorded revenue related to 81 contracts compared to 69 contracts during 2004. For the year ended December 31, 2005, $13,513,000 of revenue was the result of contracts that were in backlog at December 31, 2004 and $2,222,000 was the result of new business. For the year ended December 31, 2004,

$9,402,000 of revenue was generated from contracts that were in backlog at December 31, 2003 and $1,903,000 of revenue was the result of new business.

Direct costs of revenue, mainly personnel costs, were $3,789,000 and $2,634,000 during the years ended December 31, 2005 and 2004, respectively. Additional staff and other payroll cost increases accounted for $574,000 of the $1,155,000 increase in 2005. Third party license fees, as a result of our license agreements with Microsoft and SAS increased by $444,000 during 2005. Other direct costs, which are primarily travel and other costs billed directly to our customers, increased by $137,000 during the year ended December 31, 2005. 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 75.9% for the year ended December 31, 2005 compared to 76.7% for the year ended December 31, 2004.

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 38.7% to $10,025,000 from $7,229,000 for the years ended December 31, 2005 and 2004, respectively. Additional staff, other payroll cost increases and our sales incentive and operational performance bonus plans accounted for $695,000 of the $2,796,000 increase. Expenses related to equipment maintenance and software licensing increased $320,000 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 and licensed. Outside professional service fees, consisting of accounting and auditing, legal and consulting costs, increased by $1,302,000 during 2005. Of this $1,302,000 increase, $558,000 was related to our Sarbanes-Oxley compliance efforts, $236,000 was due to non-capitalized software development costs associated with development and modification of internal operating systems and the remainder was due to initiatives related to enhancing our sales and marketing efforts and other corporate initiatives. During the year ended December 31, 2005, $105,000 of expense was recorded as a result of our previously disclosed new director compensation program. Cost increases in all other areas, primarily related to our overall growth, resulted in additional expenses of $374,000 during the year ended December 31, 2005.

Depreciation and amortization expense increased to $748,000 during the year ended December 31, 2005, from $651,000 during the year ended December 31, 2004. The increase is due to our increased level of capital spending over the past fifteen months. From October 1, 2004 through December 31, 2005, we had capital expenditures totaling $1,758,000. This compares to $761,000 of capital expenditures in the period from June 1, 2003 through September 30, 2004.

Other income for the year ended December 31, 2005 totaled $182,000, compared to $35,000 for the year ended December 31, 2004. Other income includes interest income, which increased by $200,000. The increase in interest income was the result of the our increase in cash and cash equivalents primarily due to our December 2004 private placement of common shares and positive cash flow during 2005 along with increasing interest rates on its investments.

During 2005, we recorded an income tax benefit of $1,183,000. This was the result of a $1,200,000 decrease in our deferred tax asset valuation allowance. The decrease in our deferred tax asset valuation allowance was offset by U.S. federal alternative minimum tax of $17,000. Due to our net loss carryforwards, we had no state or local income tax expense in 2005. At December 31, 2005 we had a net operating loss carryforward of $18,869,000 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 8,077,000 Euro for German income tax purposes with no expiration date. For the three years ended December 31, 2005, we realized taxable income of approximately $1,900,000 on a cumulative basis. Given our ability to generate profits over the past three years, we believe that a full valuation allowance on our deferred tax assets is no longer necessary. However, because the EDC market is still developing, it is difficult to predict taxable income very far into the future. Therefore, the reduction in the valuation allowance of $1,200,000 recorded in 2005 reflects estimates of the next three year s taxable income based on 2005 actual results,

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with adjustments for known changes and no assumptions for growth; and therefore should not be viewed as an estimate of future earnings. At December 31, 2005, a valuation allowance of approximately $9,290,000 remains against our deferred tax assets, which consist primarily of net operating loss carryforwards for both U.S. and non-U.S income taxes. Of the $9,290,000 total allowance, approximately $5,550,000 is recorded against the portion of our deferred tax assets that represent net operating loss carryforwards for U.S income taxes, and approximately $3,480,000 is recorded against the portion of our deferred tax assets that represent net operating loss carryforwards for German income taxes.

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 was the result of new business.

Direct costs of revenue 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 being managed. 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 in 2003.

SG&A expenses increased by 30.2% 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 operational 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.

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 expenditures to a total of $1,054,000.

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.

Liquidity and Capital Resources

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

Contracts with our customers usually require a portion of the contract amount to be paid at the time the contract is initiated. Additional payments are generally received monthly as work on the contract progresses. We record all amounts received as a liability (deferred revenue) until work has been completed and revenue is recognized. Cash receipts do not necessarily correspond to costs incurred or revenue recognized. We typically receive a low volume of large-dollar receipts. Our accounts receivable will fluctuate due to the timing and size of cash receipts. Our contracting and collection practices are designed to maintain an average collection period for accounts receivable of one to three months. Any increase in our normal collection period for accounts receivable could negatively impact our cash flow from operations and our working capital. At December 31, 2005, our average collection period for accounts receivable was 56 days compared to 45 days at December 31, 2004. Accounts receivable (net of allowance for doubtful accounts) was $2,854,000 at December 31, 2005 and $1,990,000 at December 31, 2004. Deferred revenue was $1,027,000 at December 31, 2005 compared to $585,000 at December 31, 2004.

Cash and cash equivalents increased $2,175,000 during the year ended December 31, 2005. This was the result of $1,717,000 provided by operating activities, $378,000 used in investing activities and $992,000 provided by financing activities. Foreign currency fluctuations caused a $156,000 decrease in cash and cash equivalents. Cash provided by operating activities was the result of the Company s net income of $2,538,000, plus non cash operating items of $766,000. This $3,304,000 increase along with the $442,000 increase in deferred revenue was offset by the $864,000 increase in accounts receivable, which was caused by our growth in revenue during 2005, and the $1,200,000 increase in deferred tax assets. Changes in other current assets and liabilities caused cash from operating activities to increase by $35,000. Investing activities included net cash proceeds of $905,000 from purchases and maturities of short-term investments and $1,283,000 used to purchase property and equipment. Financing activities consist of net proceeds from the issuance of common shares resulting from exercises of common share options offset by costs associated with the Company s private placement of common shares and warrants to purchase its common shares.

At December 31, 2005, we had working capital of $10,796,000, and our cash, cash equivalents and short-term investments totaled $9,363,000. Our working capital has increased by $2,221,000 since December 31, 2004. The increase was the result of the $2,175,000 increase in our cash, cash equivalents, due to our cash flow from operations and sales of common shares as a result of the exercise of common share options and warrants. The current portion of our deferred tax assets increased by $287,000. Changes in other current assets and liabilities caused working capital to decrease by $241,000.

We are party to a lease agreement that requires us to maintain a restricted cash balance. Our restricted cash balance was $70,000 at December 31, 2005.

We have established a line of credit, with a bank, that allows us to borrow up to a certain percentage of our investments, as determined by the type of investment, held at the bank. The line of credit bears interest at rates based on the prime rate, and is payable on demand. We had no amounts outstanding against this line of credit at December 31, 2005.

The terms of our recently completed acquisition of ClickFind required us to pay approximately $4,000,000 of cash to the former shareholders of ClickFind in February 2006. We also issued notes payable to the former shareholders of ClickFind in the amount of $4,000,000 that bear interest at prime plus 1.0%, and are payable in installments of $500,000, $500,000 and $3,000,000 on February 1, 2007, 2008 and 2009, respectively. We are responsible for the costs of integrating ClickFind s operations with our current operations, and all future operating costs of ClickFind. During the twelve months ended December

31, 2005, Click Find recorded revenue of $1,346,000 and incurred operating costs of $1,093,000. We intend to fund these additional costs with our cash and cash equivalents, maturities of short-term investments, cash flow from operations and borrowings against our line of credit.

We intend to continue to fund the enhancement and testing of the DATATRAK EDC® software, as well invest in the development, enhancement and testing of DATATRAK eClinical . 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 2006 as we continue to build our customer base, increase our backlog and convert our current backlog into revenue. We anticipate capital and related expenditures of approximately $1,900,000 for the twelve months ending December 31, 2006, for the continued commercialization and enhancement of our two clinical trial product offerings as well as improvements to our internal operating systems. Of the $1,900,000 total, $1,100,000 is required to maintain and upgrade current systems. The remaining $800,000 is in conjunction with the anticipated growth of our business, and is to some extent discretionary. Additionally, we anticipate spending approximately $1,400,000 for maintenance of our information technology infrastructure during 2006.

Our research and development expenditures have historically been for the continued enhancement of and modifications to our DATATRAK EDC® software. For the twelve months ended December 31, 2005, we expensed approximately $1,600,000 for research and development. During 2006, we anticipate that our research and development expenditures will increase by approximately $1,500,000 to $2,000,000 compared to 2005. Our 2006 research and development expenditures will be for the continued enhancement and modifications to our DATATRAK EDC® and DATATRAK eClinical software solutions, the integration with SAS® Drug Development software and the development of our DataUnifyer product.

We expect to fund our working capital requirements from existing cash and cash equivalents, maturities of short-term investments, cash flow from operations and borrowings against our line of credit. We believe that, with the continued anticipated growth in revenue, our cash and cash equivalents, maturities of short-term investments and cash flow from operations will be sufficient to meet our working capital and capital expenditure requirements for the foreseeable future. However, we may need to raise additional funds to offset delays or cancellations of 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.

Contractual Obligations

The table below shows our contractual cash obligations, expressed in thousands, at December 31, 2005.

		Payments Due by Period			
Contractual Obligations	Total	Less than 1 year	1 3 years	3 5 years	More than 5 years
Operating leases	$ 2,787	$ 541	$ 1,066	$ 712	$ 468
Purchase obligations	150	150			
Total contractual cash obligations	$ 2,937	$ 691	$ 1,066	$ 712	$ 468

Our purchase obligations consist of the final $150,000 payment, which was made in January 2006, to SAS for access to the SAS® Drug Development software.

Our recent acquisition of ClickFind resulted in a $4,000,000 purchase obligation that was paid in February 2006, and $4,000,000 in debt obligations that will be paid in installments of $500,000, $500,000

and $3,000,000 on February 1, 2007, 2008 and 2009, respectively. These obligations are not included in our contractual obligations as of December 31, 2005.

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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

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

Interest Rate Risk

We have fixed income investments consisting of cash equivalents and short-term investments, which may be affected by changes in market interest rates. We do not use derivative financial instruments in our investment portfolio. We place our cash equivalents and short-term investments with high-quality financial institutions, limit the amount of credit exposure to any one institution and have established investment guidelines relative to diversification and maturities designed to maintain safety and liquidity. Investments are reported at amortized cost, which approximates fair value. A 1.0% change in interest rates during the year ended December 31, 2005 would have resulted in an $87,000 change in our interest income during the year.

Foreign Currency Risk

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

Our financial position and results of operations are impacted by translation adjustments caused by the conversion of foreign currency accounts and operating results into U.S. dollars for financial reporting purposes. A 1.0% fluctuation in the exchange rate between the U.S. dollar and the Euro at December 31, 2005 would have resulted in a $20,000 change in the foreign currency translation amount recorded on our balance sheet, due to foreign currency translations. A 1.0% fluctuation in the average exchange rate between the U.S. dollar and the Euro for the year ended December 31, 2005 would have resulted in a $42,000 change in our net income for the year ended December 31, 2005, due to foreign currency translations. During 2005 the average exchange rate between the Euro and the U.S. dollar increased by approximately 0.1%. The conversion of our foreign operations into U.S. dollars upon consolidation resulted in net income that was approximately $5,000 lower than would have been recorded had the exchange rate between the Euro and the U.S. dollar remained consistent with 2004 rates.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Consolidated Financial Statements

Quarterly results of operations for the year ended December 31, 2005 are included in Note 13 of the Consolidated Financial Statements.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

The Company carried out an evaluation, under the supervision and with the participation of the Company s management, including the chief executive officer and chief financial officer, of the design and operation of the Company s disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-14(e)) as of the end of the period covered by this Annual Report on Form 10-K. Based upon that evaluation, the Company s management, including the chief executive officer and chief financial officer, have concluded that, as of December 31, 2005, the Company s disclosure controls and procedures were effective to ensure that information required to be disclosed by the Company in the reports it files and submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC s rules and forms.

Management s Report on Internal Control over Financial Reporting

The management of DATATRAK International, Inc. (DATATRAK or the Company) is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. DATATRAK s internal control system was designed to provide reasonable assurance to the Company s management and Board of Directors regarding the reliability of financial reporting and the preparation and fair presentation of financial statements issued for external purposes in accordance with U.S. generally accepted accounting principles.

All internal control systems, no matter how well designed, have inherent limitations and may not prevent or detect misstatements. Therefore, even those systems determined to be effective can only provide reasonable assurance with respect to financial reporting reliability and financial statement preparation and presentation. DATATRAK s management assessed the effectiveness of the Company s internal control over financial reporting as of December 31, 2005. In making our assessment, we used the criteria set forth by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission in Internal Control Integrated Framework. Based on our assessment we believe that, as of December 31, 2005, the Company s internal control over financial reporting is effective, at the reasonable assurance level, based on the COSO criteria.

DATATRAK s independent registered public accounting firm, Ernst & Young LLP, has issued an audit report on our assessment of the Company s internal control over financial reporting which immediately follows this report.

Report of Independent Registered Public Accounting Firm On
Internal Control Over Financial Reporting

The Board of Directors and Shareholders
DATATRAK International, Inc.

We have audited management s assessment, included in the accompanying Management s Report on Internal Control over Financial Reporting, that DATATRAK International, Inc. maintained effective internal control over financial reporting as of December 31, 2005, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). DATATRAK International, Inc. s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management s assessment and an opinion on the effectiveness of the company s internal control over financial reporting based on our audit.

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

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to

the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management s assessment that DATATRAK International, Inc. maintained effective internal control over financial reporting as of December 31, 2005, is fairly stated, in all material respects, based on the COSO criteria. Also, in our opinion, DATATRAK International Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2005, based on the COSO criteria**.**

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of DATATRAK International, Inc. as of December 31, 2005 and 2004, and the related consolidated statements of operations, shareholders equity, and cash flows for each of the three years in the period ended December 31, 2005 of DATATRAK International, Inc. and our report dated February 13, 2006 expressed an unqualified opinion thereon.

ERNST & YOUNG LLP
Cleveland, Ohio
February 13, 2006

Changes in Internal Control

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

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information appearing under the captions Election of Directors and Section 16(a) Beneficial Ownership Reporting Compliance in our definitive Proxy Statement to be used in connection with our Annual Meeting of Shareholders to be held on June 8, 2006 (the 2006 Proxy Statement) is incorporated herein by reference. Information regarding our executive officers is included as Item 4A of Part I of this Annual Report on Form 10-K as permitted by Instruction 3 to Item 401(b) of Regulation S-K.

We have adopted a code of ethics, as such phrase is defined in Item 406 of Regulation S-K, that applies to all of our directors, officers and employees and all employees of our subsidiaries. The code of ethics, entitled Code of Business Conduct and Ethics, has been filed as an exhibit hereto.

Additionally, we have adopted a code of ethics, as such phrase is defined in Item 406 of Regulation S-K, that applies to our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions. The code of ethics, entitled Financial Code of Ethics, has been filed as an exhibit hereto.

ITEM 11. EXECUTIVE COMPENSATION

The information appearing under the captions Compensation of Directors, Executive Officer Compensation and Compensation Committee Interlocks and Insider Participation in the 2006 Proxy Statement is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information appearing under the captions Executive Officer Compensation and Security Ownership of Certain Beneficial Holders and Management in the 2006 Proxy Statement is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

To the extent applicable, the information appearing under the caption Certain Related Party Transactions in the 2006 Proxy Statement is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information appearing under the caption Independent Auditors in the 2006 Proxy Statement is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

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

(a)(2) Financial Statement Schedules

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

(a)(3) Exhibits

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

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

DATATRAK INTERNATIONAL, INC.

/s/ Jeffrey A. Green

Jeffrey A. Green
President and Chief Executive Officer

Date: March 13, 2006

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

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

Date: March 13, 2006

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders
DATATRAK International, Inc.

We have audited the accompanying consolidated balance sheets of DATATRAK International, Inc. and subsidiaries as of December 31, 2005 and 2004, and the related consolidated statements of operations, shareholders equity, and cash flows for each of the three years in the period ended December 31, 2005. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of DATATRAK International, Inc. and subsidiaries at December 31, 2005 and 2004, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2005, in conformity with U.S. generally accepted accounting principles.

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of DATATRAK International Inc. s internal control over financial reporting as of December 31, 2005, based on the criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 13, 2006 expressed an unqualified opinion thereon.

ERNST & YOUNG LLP
Cleveland, Ohio
February 13, 2006

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	December 31, 2005	December 31, 2004
Assets		
Current assets		
Cash and cash equivalents	$ 4,407,431	$ 2,232,276
Short-term investments	4,955,491	5,686,957
Accounts receivable, net	2,853,823	1,989,948
Deferred tax asset current	287,000	
Prepaid expenses and other current assets	702,075	488,505
Total current assets	13,205,820	10,397,686
Property and equipment		
Equipment	4,902,894	5,299,820
Leasehold improvements	618,409	614,507
	5,521,303	5,914,327
Less accumulated depreciation	3,642,899	4,491,563
	1,878,404	1,422,764
Other assets		
Restricted cash	69,976	80,611
Deferred tax asset	913,000	
Deposit	39,549	39,549
	1,022,525	120,160
Total assets	$ 16,106,749	$ 11,940,610
Liabilities and Shareholders Equity		
Current liabilities		
Accounts payable	$ 549,886	$ 185,974
Accrued expenses	832,860	1,052,301
Deferred revenue	1,027,015	584,857
Total current liabilities	2,409,761	1,823,132
Shareholders equity		
Serial Preferred Shares, without par value; authorized 1,000,000 shares; none issued		
Common shares, without par value, authorized 25,000,000; issued 13,613,161 shares as of December 31, 2005 and 13,223,791 shares as of December 31, 2004; outstanding 10,313,161 shares as of December 31, 2005 and 9,923,791	61,810,321	60,584,110

as of December 31, 2004		
Treasury shares, 3,300,000 shares at cost	(20,188,308)	(20,188,308)
Common share warrants	711,872	711,872
Accumulated deficit	(28,425,289)	(30,963,636)
Foreign currency translation	(211,608)	(26,560)
Total shareholders equity	13,696,988	10,117,478
Total liabilities and shareholders equity	$ 16,106,749	$ 11,940,610

See accompanying notes.

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Year Ended December 31,		
	2005	**2004**	**2003**
Revenue	$ 15,734,745	$ 11,305,112	$ 7,052,158
Direct costs	3,788,771	2,633,805	1,622,231
Gross profit	11,945,974	8,671,307	5,429,927
Selling, general and administrative expenses	10,025,029	7,229,433	5,550,833
Depreciation and amortization	748,358		