DATATRAK INTERNATIONAL INC
Form 10-K
March 27, 2003

Table of Contents

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

(Mark One) ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
[X] For the fiscal year ended December 31, 2002

OR

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

Commission file number 000-20699

DATATRAK International, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

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

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

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [ ]

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

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

TABLE OF CONTENTS

Table of Contents

TABLE OF CONTENTS

Table of Contents

PART I

ITEM 1. BUSINESS

General

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

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

We began EDC operations in 1997. During that year, we participated in a joint venture with IBM Global Services to develop and market a data collection and management system for use in clinical trials. The joint venture was terminated, and in January 1998, we purchased the software now known as DATATRAK EDC® from PadCom Clinical Research for $610,000. Since the purchase of DATATRAK EDC®, we have devoted the majority of our efforts to developing and improving the EDC technology employed by this software.

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

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

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

Overview of the Clinical Research Industry

Our customers are companies in the clinical pharmaceutical, biotechnology, CRO and medical device research industry. This industry is driven by regulatory requirements which mandate that clinical trial sponsors adequately test new drugs and medical devices prior to marketing these drugs and devices. As a result of these regulatory requirements, we estimate that companies in this industry spend approximately $41.0 billion annually on clinical research, including approximately $12.0 billion for the collection, analysis and management of clinical trial data.

Competitive and cost-containment pressures are forcing the pharmaceutical and biotechnology industries to become more efficient when developing new products. To improve returns on research and development investments, pharmaceutical and biotechnology companies are continuing to develop new products, while at the same time attempting to shorten product development timelines. These efforts have

Table of Contents

placed more drugs into the clinical development process and have increased the pressure for companies to develop products faster in order to maintain growth and continue to achieve acceptable returns on research and development expenditures. Clinical trial sponsors have attempted to create process efficiencies, control fixed costs and expand capacity by outsourcing clinical research activities.

DATATRAK Software and Services

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

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

DATATRAK EDC® was developed to provide clinical research data to sponsors of clinical research trials faster and more efficiently than other forms of information-processing. The DATATRAK EDC® software and its earlier versions have supported many international clinical studies involving thousands of clinical research sites and tens of thousands of patients in 39 countries. Our product suite has been utilized in the clinical development of 13 separate drugs that have received regulatory approval from either the FDA or counterpart regulatory bodies in Europe.

DATATRAK EDC® is a technology platform that consists of Windows compatible software and hardware designed to assist clinical trial sponsors in starting and finishing their clinical trials on a more timely basis. Our combination of software and hardware expedites the data collection and reporting process during a clinical trial. In addition to providing technology, we are also a service business that offers EDC and clinical trial data management capabilities across numerous research sites. Our objective is to improve the traditional process of collecting clinical research and noninterventional health care data by providing cleaner data more quickly than what is available in a paper environment. We are continually enhancing and testing the DATATRAK EDC® software and developing the DATATRAK® process. Research and development expenses were $1,680,000, $1,660,000 and $890,000 in 2002, 2001 and 2000, respectively.

The DATATRAK EDC® system consists of numerous modules designed for flexible adaptation to the clinical research process. We initially provide a set of electronic data forms that can be modeled to suit the needs of each particular clinical trial. Each form is then made available through data entry capability to each research site participating in the clinical trail via the Internet or dial-up connection. Once clinical trial data has been collected and entered, the clinical trial sponsor, or other contracted vendor, can review the data remotely via the Internet or dial-up connection. After the data is reviewed and cleansed of all entry errors, DATATRAK EDC® s report capability can generate customized reports. Finally, the software s export feature allows completed data and reports to be transmitted directly to a clinical trial sponsor s in-house

Table of Contents

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

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

Customers and Marketing

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

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

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

The extent to which we rely on revenue from one customer varies from period to period, depending upon, among other things, our ability to generate new business, the timing and size of clinical trials and other factors. In light of our small revenue base, we are more dependent on major customers than many of the larger participants in the EDC industry. The table below sets forth the revenue generated from customers who accounted for more than 10% of the Company s revenue and percentage of revenue generated by all other customers during 2002, 2001 and 2000.

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

* Less than 10% of revenue.

Contracting and Backlog

Our contracts with our customers provide a fixed price for each component or service to be delivered, and we recognize revenue as these components or services are delivered. Services provided by us that are in addition to those provided for in our contracts are billed on a fee-for-service basis as completed. Generally, these contracts range in duration from one to three years. The ultimate contract value is dependent upon the length of the customer s use of DATATRAK EDC® and the services we provide. As services are performed over the life of the contract, we recognize revenue per the specific terms of each contract. Costs associated with contract revenue are recognized as incurred. Our customers, with or without cause, can terminate a contract at any time. If one of our contracts is cancelled, we are entitled to payment for all work

Table of Contents

performed through the date of notice of termination and for recovery of some or all costs incurred to terminate a contract. The termination of a contract will not result in a material adjustment to the revenue or costs we have previously recognized.

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

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

Competition

We compete within the clinical research and the EDC markets. Both of these industries are highly competitive and fragmented. In addition, the EDC industry is currently emerging and is characterized by rapidly evolving technology. We compete in this market on the strength of DATATRAK EDC® s functionality, design architecture and data entry and review tools, which we believe equal or exceed those available in the market. We believe that we may be able to enhance our competitive strength through the formation of strategic alliances with established industry organizations. We have received expressions of interest from various parties in establishing such relationships.

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

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

Regulatory Matters

The FDA has issued guidelines and rules on the use of computer systems in clinical trials relating to standard operating procedures, data entry, system design, security, system dependability and controls, personnel training, records inspection and certification of electronic signatures. Based on our review, we

Table of Contents

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

Potential Liability and Insurance

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

If we were forced to undertake the defense of, or were found financially responsible for, claims based upon the foregoing or related risks we could incur significant costs relating to these claims. We maintain a $5.0 million errors and omissions professional liability insurance policy to cover claims that may be brought against us. This coverage may not be adequate, or continue to be available in the future.

Patents and Trademarks

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

Employees

As of February 28, 2003, we had approximately 55 full-time employees. None of our employees are represented by a union, and we consider relations with our employees to be satisfactory. We have employment agreements with all of our executive officers. Due to the early stage of development of our industry and business, the loss of the services of any of our executive officers could put us at a competitive disadvantage, since we would need to attract a qualified new executive to fill the vacancy. To address these risks, we must, among other things, continue to attract, retain and motivate qualified personnel.

ITEM 2. PROPERTIES

We presently lease approximately 10,000 square feet of office space in Mayfield Heights, a suburb of Cleveland, Ohio. This space is used for our executive offices and U.S. operations. We also lease approximately 5,000 square feet of office space in Bonn, Germany for our European operations. We believe that our facilities are suitable and adequate for the current and anticipated conduct of our operations.

ITEM 3. LEGAL PROCEEDINGS

None.

Table of Contents

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, 2002.

ITEM 4A. EXECUTIVE OFFICERS OF THE COMPANY*

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

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

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

Jeffrey A. Green, Pharm.D., FCP, is our founder and has served as our President, Chief Executive Officer and a Director since March 1992. From 1984 to 1992, Dr. Green served as an Assistant Professor of Medicine and Radiology at Case Western Reserve University, Cleveland, Ohio. During his tenure at Case Western Reserve University, Dr. Green established and directed the Cardiovascular Clinical Pharmacology Research Program at University Hospitals of Cleveland. In addition, Dr. Green was an established investigator in clinical cardiology and PET scanning, and was responsible for directing over 90 individual investigations during his tenure. Dr. Green has authored over 90 publications and has been an invited speaker at more than 170 national meetings. He was the recipient of the McKeen Cattell Distinguished Achievement Award from the American College of Clinical Pharmacology in 1988. Dr. Green is a graduate of Purdue University (B.S.) and the University of Texas (Pharm.D.).

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

Marc J. Shlaes, BB, has served as our Vice President of Research and Development since December 2000. Mr. Shlaes is responsible for the development and testing of DATATRAK EDC and our related software offerings. From October 1999 through December 2000, Mr. Shlaes served as our Vice President and Managing Director of North America. Prior to his appointment as Vice President and Managing Director of North America, Mr. Shlaes served as our Director of Technology and Services. Prior to joining us in 1998, Mr. Shlaes served in a variety of positions in the software development and delivery industry, including as an employee of International Business Machines from 1982 to 1996.

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

Table of Contents

PART II

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

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

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

Our common shares were initially offered to the public on June 11, 1996 at a price of $13.50 per share and commenced trading on Nasdaq on that date. The following table sets forth, for the fiscal years ended December 31, 2002 and 2001, the high and low sale prices per common share, as reported by Nasdaq. These prices do not include retail markups, markdowns or commissions.

	High	Low
2002		
First Quarter	$4.46	$2.30
Second Quarter	$3.70	$2.39
Third Quarter	$3.00	$1.50
Fourth Quarter	$2.00	$0.75

	High	Low
2001		
First Quarter	$4.06	$2.56
Second Quarter	$2.75	$1.50
Third Quarter	$3.40	$1.21
Fourth Quarter	$4.99	$2.30

On February 28, 2003, the last sale price of our common shares as reported by Nasdaq was $0.98 per share. As of February 28, 2003, we had 76 shareholders of record.

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

Table of Contents

ITEM 6. SELECTED FINANCIAL DATA

	Year Ended December 31,				
	2002	2001	2000	1999	1998
	(In thousands, except per share data)				
Statement of Operations Data:					
Revenue	$ 4,721	$ 2,246	$ 1,994	$ 5,811	$ 13,226
Direct costs	1,804	1,780	1,597	3,763	10,511
Gross profit	2,917	466	397	2,048	2,715
Selling, general and administrative expenses	7,893	7,210	5,726	5,871	8,969
Impairment charge					6,056
Special items	364				1,998
Depreciation and amortization	1,122	949	867	800	1,155
Loss from operations	(6,462)	(7,693)	(6,196)	(4,623)	(15,463)
Other income, net	71	339	912	14,727	1,467
(Loss) Income before income taxes	(6,391)	(7,354)	(5,284)	10,104	(13,996)
Income tax expense				384	80
Net (loss) income	$(6,391)	$(7,354)	$(5,284)	$ 9,720	$(14,076)
Net (loss) income per share: basic	$ (1.22)	$ (2.23)	$ (1.61)	$ 1.87	$ (2.19)
Shares used in the computation of basic net (loss) income per share	5,237	3,291	3,290	5,209	6,422
Net (loss) income per share: diluted	$ (1.22)	$ (2.23)	$ (1.61)	$ 1.84	$ (2.19)
Shares used in the computation of diluted net (loss) income per share	5,237	3,291	3,290	5,293	6,422

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

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

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

General

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

Table of Contents

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

Approximately 47% of our assets, or approximately $2,470,000, is held in cash, cash equivalents and short-term investments. Since commencing EDC operations in 1997, we have experienced some growth in revenue but continue to record significant losses and negative cash flow from operations. We are continuing to develop and commercialize our business, and anticipate that our operating results will fluctuate significantly from period to period.

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

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

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

Critical Accounting Policies

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

Revenue Recognition

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

Table of Contents

Software Development Costs

Development costs incurred in the research and development of new software products and enhancements to existing software products are expensed as incurred until technological feasibility has been established. After technological feasibility is established, any additional costs are capitalized in accordance with Statement of Financial Accounting Standards No. 86, Accounting for the Costs of Computer Software to be Sold, Leased, or Otherwise Marketed . Such costs are amortized over the lesser of three years or the economic life of the related product. We perform an annual review of the recoverability of such capitalized software costs. At the time a determination is made that capitalized amounts are not recoverable based on the estimated cash flows to be generated from the applicable software, any remaining capitalized amounts are expensed.

Stock Based Compensation

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

Recently Issued Accounting Standards

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

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

Results of Operations

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

Table of Contents

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

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

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

	Year Ended December 31,	
	2002	**2001**