

TABLE OF CONTENTS

[ITEM 1. BUSINESS](#)

[ITEM 2. PROPERTIES](#)

[ITEM 3. LEGAL PROCEEDINGS](#)

[ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS](#)

[ITEM 4A. EXECUTIVE OFFICERS OF THE COMPANY*](#)

[ITEM 5. MARKET FOR REGISTRANT’S COMMON SHARES AND RELATED SHAREHOLDER MATTERS](#)

[ITEM 6. SELECTED FINANCIAL DATA](#)

[ITEM 7. MANAGEMENT’S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS](#)

[ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK](#)

[ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA](#)

[ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE](#)

[ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT](#)

[ITEM 11. EXECUTIVE COMPENSATION](#)

[ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT](#)

[ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS](#)

[ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K](#)

[INDEX TO CONSOLIDATED FINANCIAL STATEMENTS](#)

[Exhibit 10.8](#)

[Exhibit 10.9](#)

[Exhibit 10.12](#)

[Exhibit 21.1](#)

[Exhibit 23.1](#)

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

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

(Mark One) ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES
EXCHANGE ACT OF 1934

☒ For the fiscal year ended December 31, 2000

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.)

20600 Chagrin Boulevard, Cleveland, Ohio

44122

(Address of principal executive offices)

(Zip code)

Registrant's telephone number, including area code: (216) 921-6505

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

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

As of February 28, 2001, the registrant had 3,290,322 Common Shares, without par value, issued and outstanding. As of that date, the aggregate market value of these shares, which together constitute all of the voting shares of the registrant, held by non-affiliates was \$10,096,483 (based upon the closing price of \$3.44 per Common Share on the Nasdaq Stock Market, Inc. on February 28, 2001). For purposes of this calculation, the registrant deems the 355,298 Common Shares beneficially held by all of its Directors and executive officers to be the Common Shares held by affiliates.

Except as otherwise stated, the information contained in this Form 10-K is as of December 31, 2000.

TABLE OF CONTENTS

	Part I	
Item 1.	Business	1
Item 2.	Properties	5
Item 3.	Legal Proceedings	5
Item 4.	Submission of Matters to a Vote of Security Holders	5
Item 4A.	Executive Officers of the Company	5
	Part II	
Item 5.	Market for Registrant’s Common Shares and Related Shareholder Matters	6
Item 6.	Selected Financial Data	7
Item 7.	Management’s Discussion and Analysis of Financial Condition and Results of Operations	7
Item 7A.	Quantitative and Qualitative Disclosures About Market Risk	15
Item 8.	Financial Statements and Supplementary Data	16
Item 9.	Changes in and Disagreements with Accountants on Accounting and Financial Disclosure	16
	Part III	
Item 10.	Directors and Executive Officers of the Registrant	16
Item 11.	Executive Compensation	16
Item 12.	Security Ownership of Certain Beneficial Owners and Management	17
Item 13.	Certain Relationships and Related Transactions	17
	Part IV	
Item 14.	Exhibits, Financial Statement Schedules, and Reports on Form 8-K	17

ITEM 1. BUSINESS

General

DATATRAK International, Inc. (“DATATRAK” or the “Company”) is an application service provider (“ASP”) that provides electronic data capture (“EDC”) and other services, which assist companies in the clinical pharmaceutical, biotechnology, contract research organization (“CRO”) and medical device research industries, in accelerating the completion of clinical trials.

The Company was founded in 1991 as a site management organization, and through its Clinical Business, which the Company no longer owns, provided clinical research services to various clinical trial sponsors. The Clinical Business was sold on April 20, 1999. DATATRAK currently operates as an ASP business providing EDC and other services to the clinical research industry.

In 1997, DATATRAK began EDC operations. During 1997, DATATRAK participated in a joint venture with IBM Global Services (“IBM”) to develop and market a data collection and management system for use in clinical trials. The joint venture was terminated, and in January 1998, the Company purchased the software now known as DATATRAK EDC™ from PadCom for \$610,000. 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 more than 50 clinical studies encompassing thousands of clinical research sites and over 28,000 patients in 31 countries. To date, the Company has devoted the majority of its efforts related to DATATRAK to further developing and improving the EDC technology employed by the DATATRAK EDC™ software.

Overview of the Clinical Research Industry

The Company’s customers are companies in the clinical pharmaceutical, biotechnology, CRO and medical device research industry. This industry is driven by regulatory requirements that clinical trial sponsors adequately test new drugs and medical devices prior to marketing. Competitive and cost-containment pressures are forcing the pharmaceutical and biotechnology industries to become more efficient in developing new products. To improve returns on research and development investments, pharmaceutical and biotechnology companies are adding products to their product pipelines and attempting to shorten the product development timeline. 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. Clinical trial sponsors have attempted to create process efficiencies, control fixed costs and expand capacity by outsourcing certain clinical research activities.

In response to similar cost-containment pressures, many hospitals, physicians and other healthcare providers have added clinical research capabilities as an additional revenue source. Clinical research allows healthcare providers to extend their core competencies and capitalize on their direct access to patients.

DATATRAK Software and Services

Under the traditional method of clinical research, clinical research associates visit research sites to review clinical data manually entered on the paper case report form for accuracy and integrity. During these physical visits, the research associate must review each page of each case report form. These monitoring 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 time duration 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™ is a technology platform that consists of Windows™ compatible software and hardware designed to assist clinical trial sponsors in starting and finishing clinical trials on a more timely basis. DATATRAK's combination of software and hardware expedites the data collection and reporting process during a clinical trial. In addition to providing technology, DATATRAK is also a service business that offers electronic data collection and clinical trial data management capabilities across numerous research sites. DATATRAK's objective is to improve the traditional process of collecting clinical research and noninterventional health care data by providing cleaner data more quickly than what is available in a paper environment.

The DATATRAK EDC™ system consists of five modules designed for flexible adaptation to the clinical research process. DATATRAK initially provides a set of electronic data forms that can be modeled to suit the needs of the clinical trial. Each form is then made available through data entry capability to each research site via the Internet or dial-up connection. Once clinical trial data has been collected and entered, the trial's 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's report capability can be accessed by customers and investigators to generate customized reports.

Finally, DATATRAK'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 physical review of paper reports.

In October 1998, an international pharmaceutical manufacturer presented clinical metrics from its use of DATATRAK EDC™ in a multicenter, international clinical trial involving 200 patients. Compared to a traditional paper model in a similar trial of size and complexity, the clinical study showed that DATATRAK EDC™ reduced overall trial duration by 30%, time to locked database by 40% and improved the "cleanliness" of the data through a significant reduction in queries by 86%. The Company believes that, by automating these procedures, the DATATRAK system can be a timesaving component of the drug development process. DATATRAK can provide any customer with the DATATRAK® process as a competitive advantage by accelerating the review and processing of clinical trial data.

Customers and Marketing

DATATRAK's market is largely comprised of clinical trial sponsors. The Company markets its software and services through its sales and marketing staff located in the United States and Europe. Since the market for EDC in general and for DATATRAK specifically has been an emerging one, the effectiveness of DATATRAK's marketing efforts has been limited. However, DATATRAK has selectively participated in scientific and medical meetings to promote its services and has occasionally used direct mail and journal advertisements to build awareness of its capabilities.

The EDC market has been slow to develop. Most EDC vendors have insignificant revenues and are classified as start-ups. The growth of the Internet over the past few years has drastically altered business strategies and pricing models in this specific sector. Nonetheless, the Company believes that automation of some sort is inevitable, and that DATATRAK EDC™ can be competitive in this emerging marketplace. The product is fully validated, web-enabled, has multilanguage capability, which has been utilized in actual clinical trials, and possesses sponsor-published metrics documenting clinical trial acceleration and enhancement of quality through significant reductions in queries.

During 2000 and 1999, Quintiles accounted for 52% and 48%, respectively of DATATRAK's EDC revenue. Aventis Pharmaceuticals accounted for 27% and 28% of DATATRAK's EDC revenue during 2000 and 1999, respectively. Bayer accounted for all of DATATRAK's 1998 EDC revenue, totaling \$130,000.

Contracting and Backlog

The Company's contracts provide a fixed price for each component or service to be delivered. Services provided by DATATRAK that are in addition to those provided for in its contracts are billed on a fee for service basis as completed. Generally, these contracts range in duration from twelve to eighteen months. The ultimate contract value is dependent upon the length of the customer's use of DATATRAK EDC™ and the services provided by DATATRAK. As services are performed over the life of the contract, revenue is recognized under the percentage of completion method utilizing units of delivery. Costs associated with contract revenues are recognized as incurred. These contracts can be terminated at any time by the customer with or without cause. DATATRAK is 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 revenue or costs previously recognized.

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

Backlog consists of anticipated revenue from letters of intent and signed contracts yet to be completed. At December 31, 2000, DATATRAK's backlog was \$3.7 million. All contracts are subject to modification and/or possible cancellation. Therefore, the amount of backlog is not necessarily indicative of the Company's future quarterly or annual revenue. Due to DATATRAK's early stage of development and its low level of backlog, we cannot assure you as to the Company's future levels of revenue.

Competition

DATATRAK competes 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 Company competes within this market on the strength of its functionality, its design architecture and its data entry and review tools, which the Company believes equal or exceed those available in the market. The Company also believes that it may enhance its competitive strength through the formation of strategic alliances with established industry organizations. The Company has received expressions of interest from various parties in establishing such relationships, but it is not engaged in any discussions concerning a sale or merger of the Company.

DATATRAK's 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 the Company's detriment. We cannot assure you that DATATRAK will be able to capture or establish the market presence necessary to effectively compete in this emerging sector of the clinical research industry, or that EDC will effectively replace paper as the preferred method of collecting and managing clinical trial data.

The Company is aware of other EDC systems that compete or, in the future, may compete directly with DATATRAK EDC™. The Company is also 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™. We cannot assure you that either existing or new competitors will not develop products that are superior to or that otherwise achieve greater market acceptance than DATATRAK EDC™. In addition, the Company believes that certain large players 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 DATATRAK's approach to EDC may gain market acceptance, we cannot assure you that larger players in the information technology industry will

not develop competing technology, or as to the effect of such competing technology on DATATRAK's operations.

Regulatory Matters

The United States Food and Drug Administration (the "FDA") has issued guidelines and rules on the use of computer systems in clinical trials. The FDA guidelines and rules relate to standard operating procedures, data entry, system design, security, system dependability and controls, personnel training, records inspection and certification of electronic signatures. Based on its review, the Company believes DATATRAK EDC™ complies with these guidelines and rules. Because the FDA's development of guidance and these rules is still in the early stages, we cannot assure you that DATATRAK EDC™ will remain consistent with the FDA's requirements. Any release of additional FDA guidance that is significantly inconsistent with the design of DATATRAK EDC™ may have a material adverse effect on the business and operations of DATATRAK. The Company intends to continue to monitor this guidance to ensure compliance.

Potential Liability and Insurance

DATATRAK's 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 testing by the Company, are discovered only after the system has been installed and used by customers. Such faults or errors could cause delays or require design modifications that could adversely affect the Company's competitive position and results of operations. 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. The Company obtains contractual agreements from its customers limiting the Company's liability for damages resulting from errors in the transportation and handling of data. Nevertheless, the Company may still be subject to significant claims for data losses in the transportation and handling of data over the Company's network.

To date, the Company has not received any claims resulting from its services, the use of DATATRAK EDC™, or the activities of its formerly owned Clinical Business. The financial position of the Company could be materially adversely affected if the Company was forced to undertake the defense of, or was found financially responsible for, claims based upon the foregoing or related risks. The Company maintains an errors and omissions professional liability insurance policy in amounts it believes to be sufficient to cover claims that may be brought against it. We cannot assure you that this coverage will be adequate, or that insurance coverage will continue to be available to the Company.

Patents and Trademarks

The Company holds registered service marks incorporating the DATATRAK® process, and various DATATRAK trademarks, including the DATATRAK EDC™ software. The DATATRAK EDC™ software is the foundation of the DATATRAK® process. Intellectual property rights are significant to the continued operation and development of the DATATRAK EDC business.

Employees

As of February 28, 2001, the Company had approximately 55 full-time employees. None of the Company's employees are represented by a union. The Company considers relations with its employees to be satisfactory. The Company has employment agreements with all of its executive officers. The loss of the services of any of its executive officers could have a material adverse effect on the business or operations of the Company. To address these risks, the Company must, among other things, continue to attract, retain and motivate qualified personnel. We cannot assure you that the Company will be successful in addressing such risks.

ITEM 2. PROPERTIES

The Company presently leases approximately 14,000 square feet of space in Cleveland, Ohio, of which approximately 6,000 square feet is sublet to an unrelated third party. The remaining 8,000 square feet are used to house the Company’s executive offices and U.S. operations. The Company is currently renegotiating the lease on approximately 7,000 square feet of office space in Bonn, Germany for its European operations.

ITEM 3. LEGAL PROCEEDINGS

None.

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, 2000.

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	45	President, Chief Executive Officer and Director
Terry C. Black	43	Vice President of Finance, Chief Financial Officer, Treasurer and Assistant Secretary
Marc J. Shlaes	46	Vice President of Research and Development
Dr. Wolfgang Summa	36	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 the Company’s founder and has served as its 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 125 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 the Company’s Vice President of Finance and Chief Financial Officer since June 1994 and has served as the Treasurer and Assistant Secretary since January 1996. Prior to joining the Company, Mr. Black served as Chief Financial Officer for Action Auto Rental, Inc., a Cleveland, Ohio based insurance replacement automobile rental company, from 1992 to 1994. Before joining Action Auto Rental, 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 the Company’s Vice President of Research and Development since December 2000. Mr. Shlaes is responsible for the development and testing of DATATRAK EDC™ and the Company’s related software offerings. From October 1999 through December 2000, Mr. Shlaes served as the Company’s Vice President and Managing Director of North America. In this position, Mr. Shlaes was responsible for the Company’s North American operational strategy, including the marketing, functionality and delivery of DATATRAK EDC™. Prior to his appointment as Vice President and Managing Director of North America, Mr. Shlaes served as the Company’s Director of Technology and

Services. In this position, Mr. Shlaes was responsible for establishing a strategy for the delivery of products and services to the Company’s customers. Prior to joining DATATRAK 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 the Company’s Vice President of Global Operations since December 2000. Dr. Summa is responsible for the Company’s operational strategy including the marketing and delivery of DATATRAK EDC™ to customers as well as the management of the Company’s clinical trials. From October 1999 through December 2000, Dr. Summa served as the Company’s Vice President and Managing Director of Europe. In this position, Dr. Summa was responsible for the Company’s European operational strategy, including the marketing, functionality and delivery of DATATRAK EDC™. From January 1998 to October 1999, Dr. Summa served as the Company’s Manager of European Operations. Prior to joining the Company, Dr. Summa served in various research positions for PadCom, including Project Manager for Eastern and Central Europe. Dr. Summa is a graduate of the University of Bonn (MSc., PhD.).

PART II

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

The Company’s Common Shares are traded on The Nasdaq National Market (“Nasdaq”) under the symbol “DATA”. The 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, 2000 and 1999, the high and low sale prices per share for the Common Shares, as reported by Nasdaq. These prices do not include retail markups, markdowns or commissions.

	High	Low
2000		
First Quarter	\$11.38	\$3.53
Second Quarter	\$ 7.13	\$3.75
Third Quarter	\$ 5.88	\$3.75
Fourth Quarter	\$ 4.88	\$2.13
1999		
First Quarter	\$ 4.91	\$4.00
Second Quarter	\$ 5.13	\$4.13
Third Quarter	\$ 5.75	\$3.75
Fourth Quarter	\$ 4.31	\$3.19

On February 28, 2001, the last sale price of the Common Shares as reported by Nasdaq was \$3.44 per share. As of February 28, 2001, there were 64 shareholders of record.

The Company has never declared or paid cash dividends on its Common Shares. Any determination to pay cash dividends in the future will be at the discretion of the Board of Directors after taking into account various factors, including the Company’s financial condition, results of operations, current and anticipated cash needs and plans for expansion.

ITEM 6. SELECTED FINANCIAL DATA

	Year Ended December 31,				
	2000	1999	1998	1997	1996
	(In thousands, except per share data)				
Statement of Operations Data:					
Revenue	\$ 1,994	\$ 5,811	\$ 13,226	\$17,327	\$25,715
Direct costs	1,597	3,763	10,511	12,637	17,976
Gross profit	397	2,048	2,715	4,690	7,739
Selling, general and administrative expenses	5,726	5,871	8,969	10,009	6,141
Impairment charge	—	—	6,056	—	—
Special items	—	—	1,998	2,995	—
Depreciation and amortization	867	800	1,155	1,015	606
Income (loss) from operations	(6,196)	(4,623)	(15,463)	(9,329)	992
Other income, net	912	14,727	1,467	1,888	1,038
Income (loss) before income taxes	(5,284)	10,104	(13,996)	(7,441)	2,030
Income tax expense (benefit)	—	384	80	(58)	383
Net income (loss)	<u>\$(5,284)</u>	<u>\$ 9,720</u>	<u>\$(14,076)</u>	<u>\$ (7,383)</u>	<u>\$ 1,647</u>
Net income (loss) per share: basic	<u>\$ (1.61)</u>	<u>\$ 1.87</u>	<u>\$ (2.19)</u>	<u>\$ (1.16)</u>	<u>\$ 0.36</u>
Shares used in the computation of basic net income (loss) per share	<u>3,290</u>	<u>5,209</u>	<u>6,422</u>	<u>6,384</u>	<u>4,626</u>
Net income (loss) per share: diluted	<u>\$ (1.61)</u>	<u>\$ 1.84</u>	<u>\$ (2.19)</u>	<u>\$ (1.16)</u>	<u>\$ 0.33</u>
Shares used in the computation of diluted net income (loss) per share	<u>3,290</u>	<u>5,293</u>	<u>6,422</u>	<u>6,384</u>	<u>5,052</u>

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

	December 31,				
	2000	1999	1998	1997	1996
	(In thousands, except per share data)				
Balance Sheet Data:					
Cash, cash equivalents and short-term investments	\$ 12,040	\$ 17,536	\$ 26,693	\$33,613	\$34,683
Working capital	11,645	16,983	24,489	33,021	39,626
Total assets	14,486	19,483	33,540	48,321	53,687
Long-term liabilities	—	—	—	—	—
Retained earnings (accumulated deficit)	(16,987)	(11,703)	(21,423)	(7,347)	36
Total shareholders' equity	13,104	18,306	28,238	42,350	49,548
Book value per common share	\$ 3.98	\$ 5.56	\$ 4.40	\$ 6.60	\$ 7.85
Cash dividends declared	—	—	—	—	—

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

General

DATATRAK is an ASP that provides EDC and other services, which assist companies in the clinical pharmaceutical, biotechnology, CRO and medical device research industries, in accelerating the completion of clinical trials. Through its Clinical Business, which the Company sold on April 20, 1999, the Company operated a multi-specialty site management organization that provided clinical research services to various clinical trial sponsors.

The discussion that follows highlights the business conditions and certain financial information specific to the Company and excluding information related to the previously owned Clinical Business.

Approximately 83% of the Company’s assets, or approximately \$12.0 million, are held in cash, cash equivalents and short-term investments. DATATRAK has recognized minimal EDC revenue to date and has experienced significant losses and negative cash flow from operations. The Company is continuing to develop and commercialize its business and anticipates that its operating results will fluctuate significantly from period to period.

DATATRAK uses 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. The Company’s future success is dependent on market acceptance of EDC in general, and acceptance of DATATRAK EDC™ specifically. We cannot assure you that the Company will be successful in achieving commercial acceptance of the DATATRAK® process.

The Company’s contracts provide a fixed price for each component or service to be delivered. Services provided by DATATRAK that are in addition to those provided for in its contracts are billed on a fee for service basis for services completed. Generally, these contracts range in duration from twelve to eighteen months. The ultimate contract value is dependent upon the length of the customer’s use of DATATRAK EDC™ and the services provided by DATATRAK. As services are performed over the life of the contract, revenue and direct costs of revenue are recognized under the percentage of completion method utilizing units of delivery. Costs associated with contract revenues are recognized as incurred. Contracts can be terminated by customers with or without cause. DATATRAK is 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 revenue or costs previously recognized.

Since its purchase of the DATATRAK EDC™ software, in January 1998, DATATRAK has recorded revenue related to a small number of contracts. At December 31, 2000, DATATRAK’s backlog was \$3.7 million. Of this backlog, \$2.8 million relates to three contracts from one customer. In the future, the Company may also record revenue related to the sales and licensing of software. Due to DATATRAK’s early stage of development and its low level of backlog, we cannot assure you as to the Company’s future levels of revenue.

Results of Operations

The following tables set forth, for the periods indicated, certain items from the Company’s Consolidated Statements of Operations, expressed in thousands, excluding information related to the operations of the previously owned Clinical Business.

	Year Ended December 31,		
	2000	1999	1998
Revenue	\$ 1,994	\$ 900	\$ 132
Direct costs	1,597	766	464
Gross profit (loss)	397	134	(332)
Selling, general and administrative expenses	5,726	4,381	4,070
Special items	—	—	753
Depreciation and amortization	867	671	470
Loss from operations	(6,196)	(4,918)	(5,625)
Other income, net	912	14,727	1,467
Income (loss) before income taxes	(5,284)	9,809	(4,158)
Income tax expense	—	384	80
Net income (loss)	<u>\$(5,284)</u>	<u>\$ 9,425</u>	<u>\$(4,238)</u>

Year ended December 31, 2000 Compared with Year ended December 31, 1999

Revenue for the year ended December 31, 2000 increased by 122.2% to \$2.0 million as compared to \$900,000 for the year ended December 31, 1999. Of this increase, \$900,000 is from customers that the Company established relationships with in 1999, the remainder of the increase results from contracts with new customers.

Direct costs of revenue, mainly personnel costs, were \$1.6 million and \$770,000 during the years ended December 31, 2000 and 1999, respectively. The 107.8% increase in direct costs was mainly the result of increased personnel costs of \$540,000 from the addition of employees. The remaining increase was due to additional contract costs related to the increased usage of the DATATRAK EDC™ software. During 2000, the Company completed a study of employee and other costs involved with research and development activities. Such research and development costs for 1999, totaling \$260,000 were reclassified from direct costs to selling, general and administrative expenses to conform to the 2000 reporting presentation.

Selling, general and administrative expenses (“SG&A”) include all administrative personnel costs, business development costs, and all other expenses not directly chargeable to a specific contract. These expenses increased by 29.6% to \$5.7 million from \$4.4 million for the years ended December 31, 2000 and 1999, respectively. The increase was primarily due to increased personnel costs of \$930,000. Included in the \$930,000 increase in personnel costs is a one-time, non-cash charge of \$110,000 for compensation expense on stock options, which have exercise prices below market value on the shareholder approval date. Other SG&A costs associated with the development of and marketing of DATATRAK increased by \$350,000. A one-time expense of \$350,000 associated with services to assess the market potential of the DATATRAK EDC™ software is included in 1999 SG&A. The absence of this expense was offset by \$370,000 of additional consulting costs in 2000.

Depreciation and amortization expense increased to \$870,000 during the year ended December 31, 2000 from \$670,000 during the year ended December 31, 1999. The increase was the result of depreciating capital expenditures associated with the building of DATATRAK’s information technology infrastructure.

Other income for the year ended December 31, 2000 totaled \$910,000 compared to \$14.7 million for the year ended December 31, 1999. During 1999, a \$12.2 million gain was recorded associated with the sale of the Clinical Business, and \$1.3 million was received as the result of a favorable outcome in a lawsuit. Other income also includes interest income which decreased \$430,000 in 2000, compared to the year ended December 31, 1999, due to the Company’s use of cash to fund its repurchase of Common Shares in August 1999, operating losses and other working capital needs.

Due to the Company’s loss for the year ended December 31, 2000, no income tax expense was recorded. At December 31, 2000, the Company had a net operating loss carryforward of approximately \$11.4 million, which will expire in the year 2020. The Company also had a net operating loss carryforward of approximately \$3.3 million, for German tax purposes, with no expiration date.

Year ended December 31, 1999 Compared with Year ended December 31, 1998

Revenue for the year ended December 31, 1999 increased to \$900,000 as compared to \$130,000 for the year ended December 31, 1998. Of the \$770,000 increase, \$680,000 is the result of revenue associated with contracts from two new customers. The remainder of the increase is due to an increase in the number and size of contracts being executed by DATATRAK, resulting from the increasing acceptance of DATATRAK EDC™.

Direct costs of revenue increased 67.4% to \$770,000 for the year ended December 31, 1999 as compared to \$460,000 for the year ended December 31, 1998. The increase in direct costs was the result of \$310,000 in additional contract costs related to the increased usage of the DATATRAK EDC™ software.

SG&A expenses were \$4.4 million and \$4.1 million for the years ended December 31, 1999 and 1998, respectively. Corporate overhead expenses decreased by \$520,000 as a result of the Company's first quarter of 1998 reorganization and the April 1999 sale of the Clinical Business. This decrease was offset by increased personnel, research and development and other continuing expenses of \$470,000 associated with the development of DATATRAK. A one-time expense of \$350,000 associated with services to assess the market potential of the DATATRAK EDC™ software is included in 1999 SG&A costs.

DATATRAK had special charges of \$750,000 during the year ended December 31, 1998. Of these charges, \$620,000 resulted from the Company's first quarter 1998 reorganization and included severance costs for ten employees who were terminated in March 1998. The remaining \$130,000 related to costs associated with the termination of the technology alliance agreement between the Company and IBM. When the technology alliance agreement was terminated, the Company and IBM disagreed on a number of issues concerning the parties' financial responsibilities. As a result of this disagreement the Company wrote off software and licenses associated with the technology alliance.

Depreciation and amortization expense increased to \$670,000 during the year ended December 31, 1999 from \$470,000 during the year ended December 31, 1998. The increase was the result of depreciating capital expenditures associated with the building of DATATRAK's information technology infrastructure.

During the year ended December 31, 1999, other income totaled \$14.7 million compared to \$1.5 million for the year ended December 31, 1998. The increase was primarily the result of the \$12.2 million gain associated with the sale of the Clinical Business, and \$1.3 million received as the result of a favorable outcome in a lawsuit. The lawsuit was related to an attempted acquisition of U-Gene Research B.V. ("U-Gene"). Other income also includes interest income which decreased \$370,000 in 1999, compared to the year ended December 31, 1998, due to the Company's use of cash to fund its repurchase of Common Shares, operating losses and other working capital needs.

Income tax expense of \$380,000 for the year ended December 31, 1999 is the result of federal alternative minimum taxes and state income taxes incurred related to the gain associated with the sale of the Clinical Business and the \$1.3 million received from a favorable ruling in the Company's lawsuit against U-Gene. During 1998, the Company incurred state income taxes of \$80,000.

Liquidity and Capital Resources

Since its inception, the Company's principal sources of cash have been cash flow from operations and proceeds from the sale of equity securities. During 1999, the Company also generated \$15.6 million in cash through the sale of its Clinical Business and \$1.3 million in cash from a favorable legal settlement. The Company's investing activities primarily reflect capital expenditures and net purchases of short-term investments. Also, during 1999, the Company repurchased 3.3 million of its Common Shares at a cost of \$20.2 million.

The Company's contracts usually require a portion of the contract amount to be paid at the time the contract is initiated. Additional payments are generally received upon completion of negotiated performance milestones throughout the life of the contract. All amounts received are recorded 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. The Company typically receives a low volume of large-dollar receipts. Accounts receivable will fluctuate due to the timing and size of cash receipts. Accounts receivable (net of allowance for doubtful accounts) was \$610,000 at December 31, 2000 and \$330,000 at December 31, 1999. Deferred revenue was \$340,000 at December 31, 2000 and \$30,000 at December 31, 1999.

Cash and cash equivalents decreased \$580,000 during the year ended December 31, 2000. This was the result of \$4.6 million provided by investing activities, \$5.2 million being used by operating activities. Cash used for operating activities resulted from the funding of net operating losses and other working capital needs. Investing activities include \$5.6 million provided by net maturities of short-term investments and \$1.0 million used to purchase equipment.

At December 31, 2000, the Company had working capital of \$11.6 million, and its cash, cash equivalents and short-term investments totaled \$12.0 million. The Company's working capital decreased by \$5.3 million from December 31, 1999. The decrease was primarily the result of a \$5.5 million decrease in the Company's cash, cash equivalents and short-term investments.

The Company is responsible for funding the future development and testing of the DATATRAK EDC™ software. The Company will continue to invest in the development of the DATATRAK® process. The Company's operations and the EDC market are still in a developmental stage. DATATRAK has experienced marginal revenue growth, however the Company anticipates negative cash flow from operations during 2001, as it continues to build its operational and business development infrastructure. The Company anticipates capital and related expenditures of approximately \$2.0 million over the next twelve months for continued commercialization and product development of DATATRAK EDC™, which the Company expects to fund from existing cash and cash equivalents, maturities of short-term investments and cash flow from operations. The Company believes that its cash and cash equivalents, maturities of short-term investments and cash flow from operations, together with its existing sources of equity, will be sufficient to meet its working capital and capital expenditure requirements for the next year. However, at the current rates of negative cash flows, capital and related expenditures and revenue growth, the Company anticipates that in 2002 it may need to raise additional funds for working capital by selling debt or equity securities or through other arrangements. Additional capital may not be available on acceptable terms, if at all.

Inflation

To date, the Company believes the effects of inflation have not had a material adverse effect on its results of operations or financial condition.

Interest Rate Risk

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

Foreign Currency Risk

The Company's foreign sales and results of operations are subject to the impact of foreign currency fluctuations. Approximately 23% of the Company's 2000 revenue was earned in Germany. The Company manages its risk to foreign currency exchange rates by maintaining foreign currency bank accounts in currencies in which it regularly transacts business. The Company does not currently hedge against the risk of exchange rate fluctuations.

Euro Currency Conversion

On January 1, 1999, eleven of the fifteen members of the European Union adopted a new European currency unit (the "Euro") as their common legal currency. The participating countries' national currencies will remain legal tender as denominations of the Euro from January 1, 1999 through January 1, 2002, and the exchange rates between the Euro and such national currency units will be fixed. The conversion to the Euro is not expected to have a material impact on the Company's financial position, results of operations or cash flows. However, uncertainty exists as to the effects the Euro will have on the marketplace.

INFORMATION ABOUT FORWARD-LOOKING STATEMENTS

Certain statements made in this Annual Report on Form 10-K contain certain forward-looking statements that are based on management's current beliefs, estimates and assumptions concerning the operations, future results and prospects of DATATRAK and the clinical pharmaceutical research industry in general. All statements that address operating performance, events or developments that management anticipates 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 within the meaning of Section 21E of the Securities Exchange Act of 1934 ("Exchange Act"). 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.

Any number of factors could affect future operations and results. The Company has identified the following important factors, which could cause the Company's actual operational or financial results to differ materially from any projections, estimates, forecasts or other forward-looking statements made by or on behalf of the Company. 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 made by the Company. DATATRAK undertakes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Limited Operating History; Lack of Profitable Operations

The Company began providing EDC services in 1997 and has a limited operating history upon which investors may evaluate its performance. DATATRAK has recognized operating losses in each year since 1997. We cannot assure you that the Company will be profitable during future periods.

Continuing Development of DATATRAK EDC™; Ability to Absorb Corporate Overhead

Although the DATATRAK EDC™ software has been used in clinical trials, its continued development is necessary. To date the Company has had minimal EDC revenue from which to support the costs of this continued development. There can be no guarantee of DATATRAK's potential future revenue, or its ability to absorb its corporate overhead and other fixed operating costs that will be necessary for the success of the DATATRAK® process.

Fluctuations in Quarterly Results

The Company is subject to significant fluctuations in quarterly results caused by many factors, including the Company's success in obtaining new contracts, the size and duration of the clinical trials in which the Company participates, the timing of clinical trial sponsor decisions to conduct new clinical trials or cancel or delay ongoing trials and other factors. As a result of DATATRAK's limited operating history, the Company does not have historical financial data for a significant number of periods on which to base planned operating expenses. Therefore, the Company's expense levels are based in part on its expectations as to future revenue and to a certain extent are fixed. We cannot assure you as to the Company's revenue in any given period, and it may be unable to adjust expenses in a timely manner to compensate for any unexpected revenue shortfall. As a result of the Company's relatively small revenue base, any significant shortfall in revenue recognized during a particular period could have an immediate adverse effect on its results of operations and financial condition. We cannot assure you that the Company will be able to accurately anticipate quarterly results. Volatility in the Company's quarterly results may adversely affect the market price of the Common Shares.

Risks Associated with Unproven Business Strategies and Early Stage of the Company's Development

The Company's 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 the Company's business remains unproven. We cannot assure you that the Company's strategy will continue to gain acceptance among sponsors, research sites or investigators. The Company's 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, and we cannot assure you that the Company will be successful in these efforts.

Potential Delay or Loss of Contracts

Although the Company's contracts provide that it is entitled to receive revenue earned through the date of termination, customers generally are free to delay or terminate a clinical trial or the Company's contract related thereto at any time. The length of a typical clinical trial contract varies from several months to several years. Clinical trial sponsors may delay or terminate clinical trials for several reasons, including unexpected results or adverse patient reactions to a potential product, inadequate patient enrollment or investigator recruitment, manufacturing problems resulting in shortages of a potential product or decisions by the sponsor to de-emphasize or terminate a particular trial or drug. A clinical trial sponsor's decision to delay or terminate a trial in which the Company participates could have a material adverse effect on the Company's business, results of operations and financial condition.

Dependence on Major Customers

The Company's primary customers are companies in the pharmaceutical industry. The Company's business is substantially dependent on the research and development expenditures of companies in this industry. During 2000 and 1999, Quintiles accounted for 52% and 48%, respectively of DATATRAK's EDC revenue. Aventis Pharmaceuticals accounted for 27% and 28% of DATATRAK's EDC revenue during 2000 and 1999, respectively. Bayer accounted for all of DATATRAK's 1998 EDC revenue, totaling \$130,000. The extent to which the Company relies on revenue from one customer varies from period to period, depending upon, among other things, its ability to generate new business, the timing and size of clinical trials and other factors. In light of the Company's small revenue base, it is more dependent on major customers than many of the larger participants in the EDC industry. The Company's 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 their research and development expenditures or a change in the regulatory environment in which these companies operate.

Management of Growth; Need for Improved Systems

The Company believes that the expansion of its business will continue to place a strain on its operational, human and financial resources. In order to manage such expansion, the Company must continue to improve its operating, administrative and information systems and accurately predict its future personnel and resource needs. In addition, expansion of foreign operations also may involve the additional risks of assimilating differences in foreign business practices, hiring and retaining qualified personnel and overcoming language barriers. Failure by the Company to meet the demands of and to manage expansion of its business and operations could have a material adverse effect on the Company's business, results of operations and financial condition.

Dependence on Key Personnel

As of February 28, 2001, the Company had approximately 55 full-time employees. The Company's growth continues to place significant demands on its management resources. The success of the Company's business is dependent on the services of its senior management team. The Company has employment agreements with all of its executive officers. The loss of the services of any of its executive

officers could have a material adverse effect on the Company. The Company's performance depends on its ability to attract and retain qualified personnel. The level of competition among employers for skilled personnel is high. We cannot assure you that the Company will be able to continue to attract and retain qualified personnel.

Government Regulation; Potential Impact of Health Care Reform

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

The FDA's guidelines and rules related to the use of computerized systems in clinical trials are still in the early stages of development. We cannot assure you that the DATATRAK® process can be kept in compliance with these guidelines and rules as they develop. Any release of FDA guidance that is significantly inconsistent with the design of DATATRAK EDC™ may have a material adverse effect on the business and operations of DATATRAK.

Competition

The EDC market, which is still developing, and must compete with the traditional paper method of collecting clinical trial data, is highly fragmented. The major competitors, in the EDC market, include EDC software vendors, clinical trial data service companies and in-house development efforts within large pharmaceutical companies. Any current and potential future competitors have or may have substantially greater resources, greater name recognition and more extensive customer bases that could be leveraged, thereby gaining market share or product acceptance to the Company's detriment. We cannot assure you that the Company will be able to capture or establish the market presence necessary to effectively compete in this emerging sector of the clinical research industry.

Potential Liability from Operations

DATATRAK's 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. To date, DATATRAK has not received any claims resulting from either errors in data handling or professional malpractice. The Company maintains an errors and omissions professional liability policy it believes to be sufficient to cover claims that may be brought against it. We cannot assure you that this coverage will be adequate or that insurance will continue to be available.

Demand for and Market Acceptance of the Internet and its Infrastructure Development

The increased use of the Internet for retrieving, sharing and transferring information among businesses, consumers, suppliers and partners, and for Internet content delivery services has only begun to develop in recent years. DATATRAK's success will depend in large part on continued growth in the use of the Internet. Critical issues concerning the commercial use of the Internet remain unresolved and are likely to affect the development of the market for the Company's services. The adoption of the Internet for information retrieval and exchange, commerce and communications generally will require the acceptance of a new medium of conducting business and exchanging information. Demand for and market acceptance of the Internet are subject to a high level of uncertainty and are dependent on a number of factors. If the

market for Internet content delivery services or the Internet as a commercial or business medium does not develop, or develops more slowly than expected, the Company's business, results of operations and financial condition could be adversely affected.

Anti-takeover Provisions, Preferred Share Purchase Rights

The Company's Articles of Incorporation and By-Laws contain provisions that may discourage a third party from acquiring, or attempting to acquire the Company. These provisions could limit the price that certain investors might be willing to pay for Common Shares. In addition, Preferred Shares can be issued by the Company's Board of Directors, without shareholder approval, whether under the Company's 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 the Common Shares and may make it more difficult for a third party to acquire a majority of the outstanding Common Shares. At the present time, the Company does not plan to issue any Preferred Shares.

General Economic Conditions

To date the Company believes that conditions such as the rate of employment, inflation, interest rates, and the condition of the capital markets have not had a material adverse effect on its results of operations or financial condition. However any change in these conditions could adversely effect the carrying value of the Company's short-term investments, its results of operations or financial condition.

Foreign Currency

The Company's foreign sales and results of operations are subject to the impact of fluctuations in foreign currency exchange rates. The Company manages its exposure to foreign currency exchange rates by maintaining foreign currency bank accounts in currencies in which the Company regularly transacts business. The Company does not currently hedge against the risk of foreign currency exchange rate fluctuations. Any adverse change in foreign currency exchange rates for those currencies in which the Company regularly transacts business could have a material adverse effect upon the Company's business, results of operations and financial condition.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

The Company is exposed to market risk from changes in interest rates and foreign currency exchange rates since it funds its operations through long-and short-term investments and has business transactions in German Deutschmarks. A summary of the Company's primary market risk exposures is presented below.

Interest Rate Risk

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

Foreign Currency Risk

The Company's foreign sales and results of operations are subject to the impact of foreign currency fluctuations. Approximately 23% of the Company's 2000 revenue was earned in Germany. The Company manages its risk to foreign currency exchange rates by maintaining foreign currency bank accounts in currencies in which it regularly transacts business. The Company does not currently hedge against the risk of exchange rate fluctuations.

Euro Currency Conversion

On January 1, 1999, eleven of the fifteen members of the European Union adopted a new European currency unit (the “Euro”) as their common legal currency. The participating countries’ national currencies will remain legal tender as denominations of the Euro from January 1, 1999 through January 1, 2002, and the exchange rates between the Euro and such national currency units will be fixed. The conversion to the Euro is not expected to have a material impact on the Company’s financial position, results of operations or cash flows. However, uncertainty exists as to the effects the Euro will have on the marketplace.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Index to Consolidated Financial Statements

	<u>Page</u>
Report of Independent Auditors	F-2
Consolidated Balance Sheets at December 31, 2000 and 1999	F-3
Consolidated Statements of Operations for each of the three years in the period ended December 31, 2000	F-4
Consolidated Statements of Shareholders’ Equity for each of the three years in the period ended December 31, 2000	F-5
Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2000	F-6
Notes to Consolidated Financial Statements	F-7

Quarterly results of operations for the year ended December 31, 2000 are included in Note 15 of the Consolidated Financial Statements.

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

None.

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT

The information regarding Directors appearing under the caption “Election of Directors” in the Company’s definitive Proxy Statement to be used in connection with the Annual Meeting of Shareholders to be held on June 1, 2001 (the “2001 Proxy Statement”) is incorporated herein by reference. Information required by this Item as to the executive officers of the Company is included as Item 4A of Part I of this Annual Report on Form 10-K as permitted by Instruction 3 to Item 401(b) of Regulation S-K. Information required by Item 405 of Regulation S-K is set forth in the 2001 Proxy Statement under the heading “Section 16(a) Beneficial Ownership Reporting Compliance,” which information is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item is incorporated herein by reference to “Executive Compensation” in the 2001 Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information required by this Item is incorporated herein by reference to “Security Ownership of Principal Holders and Management” in the 2001 Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

To the extent applicable, the information required by this Item is incorporated herein by reference to “Compensation Committee Interlocks and Insider Participation” and “Certain Transactions” in the 2001 Proxy Statement.

PART IV

ITEM 14. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(a)(1) Financial Statements

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

(a)(2) Financial Statement Schedules

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

(a)(3) Exhibits

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

(b) Reports on Form 8-K.

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

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 23, 2001

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

Date: March 23, 2001

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

	<u>Page</u>
DATATRAK International, Inc. and Subsidiaries	
Report of Independent Auditors	F-2
Consolidated Balance Sheets at December 31, 2000 and 1999	F-3
Consolidated Statements of Operations for each of the three years in the period ended December 31, 2000	F-4
Consolidated Statements of Shareholders' Equity for each of the three years in the period ended December 31, 2000	F-5
Consolidated Statements of Cash Flows for each of the three years in the period ended December 31, 2000	F-6
Notes to Consolidated Financial Statements	F-7

REPORT OF INDEPENDENT AUDITORS

The Board of Directors and Shareholders
DATATRAK International, Inc.

We have audited the accompanying consolidated balance sheets of DATATRAK International, Inc. and subsidiaries (the “Company”) as of December 31, 2000 and 1999, and the related consolidated statements of operations, shareholders’ equity, and cash flows for each of the three years in the period ended December 31, 2000. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of DATATRAK International, Inc. and subsidiaries at December 31, 2000 and 1999, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2000, in conformity with accounting principles generally accepted in the United States.

ERNST & YOUNG LLP

Cleveland, Ohio
February 2, 2001

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2000	1999
Assets		
Current assets		
Cash and cash equivalents	\$ 2,383,244	\$ 2,961,403
Short-term investments	9,656,852	14,575,071
Accounts receivable, net	609,351	334,645
Taxes receivable	130,386	19,730
Notes receivable - current	6,114	6,650
Prepaid expenses	240,712	262,636
Total current assets	13,026,659	18,160,135
Property and equipment		
Equipment	3,160,914	2,182,141
Leasehold improvements	135,669	135,669
	3,296,583	2,317,810
Less accumulated depreciation	1,922,231	1,060,252
	1,374,352	1,257,558
Other assets		
Notes receivable - long term	76,607	56,767
Other assets	8,382	8,933
	84,989	65,700
Total assets	\$ 14,486,000	\$ 19,483,393
Liabilities and Shareholders' Equity		
Current liabilities		
Accounts payable	\$ 129,038	\$ 281,867
Accrued expenses	914,114	864,569
Deferred revenue	338,879	30,960
Total current liabilities	1,382,031	1,177,396
Shareholders' equity		
Serial Preferred Shares, without par value; authorized 1,000,000 shares; none issued	—	—
Common shares, without par value, authorized 15,000,000 shares; issued 6,590,322 shares as of December 31, 2000 and December 31, 1999; outstanding 3,290,322 shares as December 31, 2000 and December 31, 1999	50,356,667	50,236,553
Accumulated deficit	(16,987,206)	(11,703,459)
Treasury shares, 3,300,000 shares at cost	(20,188,308)	(20,188,308)
Foreign currency translation	(77,184)	(38,789)
Total shareholders' equity	13,103,969	18,305,997
Total liabilities and shareholders' equity	\$ 14,486,000	\$ 19,483,393

See accompanying notes.

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	For the Year Ended December 31,		
	2000	1999	1998
Revenue	\$ 1,993,785	\$ 5,811,165	\$ 13,226,078
Direct costs	<u>1,596,355</u>	<u>3,762,843</u>	<u>10,511,024</u>
Gross profit	397,430	2,048,322	2,715,054
Selling, general and administrative expenses	5,725,846	5,870,869	8,968,913
Impairment charge	—	—	6,056,019
Special items	—	—	1,998,187
Depreciation and amortization	<u>867,484</u>	<u>800,495</u>	<u>1,155,110</u>
Loss from operations	(6,195,900)	(4,623,042)	(15,463,175)
Other income (expense):			
Interest income	888,385	1,313,427	1,679,260
Gain on sale of Clinical Business	—	12,154,827	—
Other income (expense)	<u>23,768</u>	<u>1,258,330</u>	<u>(212,307)</u>
Income (loss) before income taxes	(5,283,747)	10,103,542	(13,996,222)
Income tax expense	<u>—</u>	<u>384,000</u>	<u>80,000</u>
Net income (loss)	<u><u>\$(5,283,747)</u></u>	<u><u>\$ 9,719,542</u></u>	<u><u>\$(14,076,222)</u></u>
Net income (loss) per share:			
Basic:			
Net income (loss) per share	<u><u>\$ (1.61)</u></u>	<u><u>\$ 1.87</u></u>	<u><u>\$ (2.19)</u></u>
Weighted average shares outstanding	<u><u>3,290,322</u></u>	<u><u>5,208,535</u></u>	<u><u>6,421,820</u></u>
Diluted:			
Net income (loss) per share	<u><u>\$ (1.61)</u></u>	<u><u>\$ 1.84</u></u>	<u><u>\$ (2.19)</u></u>
Weighted average shares outstanding	<u><u>3,290,322</u></u>	<u><u>5,293,486</u></u>	<u><u>6,421,820</u></u>

See accompanying notes.

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

	Common Shares		Treasury Shares		Retained Earnings (Accumulated Deficit)	Foreign Currency Translation Adjustments	Total
	Number of Shares	Stated Amount	Number of Shares	Cost			
Balance at January 1, 1998	6,412,872	49,697,057	—	—	(7,346,779)	—	42,350,278
Exercise of Common Share Options	10,000	2,100					2,100
Stock compensation		5,585					5,585
Comprehensive loss:							
Foreign currency translation						(44,041)	(44,041)
Net loss					(14,076,222)		(14,076,222)
Comprehensive loss					(14,076,222)	(44,041)	(14,120,263)
Balance at December 31, 1998	6,422,872	49,704,742	—	—	(21,423,001)	(44,041)	28,237,700
Exercise of Common Share Options	167,450	510,111					510,111
Stock compensation		21,700					21,700
Tender of Common Shares	(3,300,000)		3,300,000	(20,188,308)			(20,188,308)
Comprehensive income:							
Foreign currency translation						5,252	5,252
Net income					9,719,542		9,719,542
Comprehensive income					9,719,542	5,252	9,724,794
Balance at December 31, 1999	3,290,322	50,236,553	3,300,000	(20,188,308)	(11,703,459)	(38,789)	18,305,997
Stock compensation		120,114					120,114
Comprehensive loss:							
Foreign currency translation						(38,395)	(38,395)
Net loss					(5,283,747)		(5,283,747)
Comprehensive loss					(5,283,747)	(38,395)	(5,322,142)
Balance at December 31, 2000	3,290,322	\$50,356,667	3,300,000	\$(20,188,308)	\$(16,987,206)	\$(77,184)	\$ 13,103,969

See accompanying notes

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Year Ended December 31,		
	2000	1999	1998
Operating Activities			
Net income (loss)	\$ (5,283,747)	\$ 9,719,542	\$(14,076,222)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Gain on sale of Clinical Business	—	(12,154,827)	—
Depreciation and amortization	867,484	800,495	1,155,110
Accretion of discount on investments	(748,790)	(1,115,730)	(1,469,481)
Stock compensation	120,114	21,700	5,585
Other	49,373	100,536	3,039
Impairment charge	—	—	6,056,019
Special items	—	—	1,998,187
Changes in operating assets and liabilities:			
Accounts and taxes receivable	(401,862)	(370,648)	1,861,785
Prepaid expenses	21,924	(40,867)	253,050
Other assets	551	7,240	13,560
Accounts payable and accrued expenses	(103,284)	(2,056,527)	(2,445,660)
Deferred revenue	307,919	(279,449)	(227,064)
Net cash used in operating activities	(5,170,318)	(5,368,535)	(6,872,092)
Investing Activities			
Purchases of property and equipment	(1,029,494)	(746,434)	(1,646,430)
Sale of business (net of cash sold)	—	15,601,184	—
Maturities of short-term investments	48,385,285	242,206,142	71,870,122
Purchases of short-term investments	(42,718,276)	(233,044,816)	(65,789,332)
Other	—	4,625	7,802
Net cash provided by investing activities	4,637,515	24,020,701	4,442,162
Financing Activities			
Purchase of treasury shares	—	(20,188,308)	—
(Issuance) repayment of notes receivable	(19,304)	(63,417)	165,000
Proceeds from issuance of shares	—	510,111	2,100
Net cash (used in) provided by financing activities	(19,304)	(19,741,614)	167,100
Effect of exchange rate on cash	(26,052)	(21,735)	(46,096)
Increase (decrease) in cash and cash equivalents	(578,159)	(1,111,183)	(2,308,926)
Cash and cash equivalents at beginning of year	2,961,403	4,072,586	6,381,512
Cash and cash equivalents at end of year	\$ 2,383,244	\$ 2,961,403	\$ 4,072,586
Cash paid during the year for interest	\$ —	\$ —	\$ —
Net cash paid during the year for income taxes	\$ 103,795	\$ 192,170	\$ 51,341

See accompanying notes.

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
For the Years Ended December 31, 1997, 1998 and 1999

1. Accounting Policies

Description of Business

DATATRAK International, Inc. (“DATATRAK” or the “Company”) is an Application Service Provider (“ASP”) that provides electronic data capture (“EDC”) and other services, which assist companies in the clinical pharmaceutical, biotechnology, contract research organization (“CRO”) and medical device research industries, to accelerate the completion of clinical trials. Prior to April 20, 1999, the Company also managed a network of non-owned affiliated and owned clinical research sites, which provided Phase I through IV clinical research services, and over the counter product services (the “Clinical Business”). The Clinical Business was sold on April 20, 1999.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All significant intercompany accounts and transactions have been eliminated in consolidation.

Revenue Recognition

DATATRAK — DATATRAK contracts provide a fixed price for each component or service to be delivered. Services provided by DATATRAK that are in addition to those provided for in its contracts are billed on a fee for service basis as services are completed. Revenue and related direct costs of revenue are recognized as services are performed under the percentage of completion method utilizing units of delivery. Pass-through costs that are paid directly by the Company’s clients, and for which the Company does not bear the risk of economic loss, are excluded from revenue. The termination of a contract will not result in a material adjustment to the revenue or costs previously recognized. DATATRAK is also a seller and licensor of software. Generally, revenue is recognized upon delivery of sold software. Licensing revenue is recognized ratably over the life of the license. To date DATATRAK has not recognized any revenue from software sales.

Clinical Business — Revenue and related direct costs of revenue were recognized as specific contract terms were fulfilled under the percentage of completion method (the units of delivery method). Fees for individual contract services were fixed upon execution of the contract and provided for payment for all work performed.

Concentration of Credit Risk

The Company is subject to credit risk through accounts receivable and short-term investments. The Company generally does not require collateral and the majority of its accounts receivable are unsecured. Short-term investments are placed with high credit-quality financial institutions or in short-duration with high credit-quality debt securities. The Company limits the amount of credit exposure in any one institution or type of investment instrument.

Cash Equivalents

The Company considers all highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. Investments in cash equivalents are carried at cost which approximates market value.

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — Continued
For the Years Ended December 31, 2000, 1999 and 1998

Short-term Investments

Short-term investments are comprised of U.S. Treasury securities and obligations of U.S. government agencies, obligations of states and other political subdivisions, and U.S. corporate obligations with maturities of one year or less. These securities are stated at amortized cost, which approximates fair value. The Company has the positive intent and ability to hold the securities to maturity.

Property and Equipment

Property and equipment are stated at cost. Depreciable assets consist of medical, office, and computer equipment, software, and software development costs and leasehold improvements. Depreciation and amortization on medical, office, and computer equipment and software, and software development costs is computed using the straight-line method over estimated useful lives of 3 to 7 years. Leasehold improvements are amortized using the straight-line method over the lesser of the assets' estimated useful life or the lease term. Depreciation and amortization expense related to depreciable assets was \$870,000, \$780,000 and \$820,000 for 2000, 1999 and 1998, respectively.

Deferred Revenue

Deferred revenue represents cash advances received in excess of revenue earned on on-going contracts. Payment terms vary with each contract but may include an initial payment at the time the contract is executed, with future payments dependent upon the completion of certain contract phases or targeted milestones. In the event of contract cancellation, the Company is entitled to payment for all work performed through the point of cancellation.

Stock Based Compensation

The Company accounts for stock based compensation in accordance with Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25").

Impairment of Long-Lived Assets

The Company evaluates impairment of long-lived assets in accordance with Financial Accounting Standards Board Statement No. 121, "Accounting for the Impairment of Long-Lived Assets and for Long-Lived Assets to Be Disposed Of" ("SFAS 121"). As such, the carrying values of long-lived assets are evaluated if circumstances indicate a possible impairment in value. If undiscounted cash flows over the remaining amortization period indicate that long-lived assets may not be recoverable, the carrying value will be reduced by the estimated shortfall of cash flows on a discounted basis. (See Note 4).

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that might affect the amounts reported in the financial statements and accompanying notes. Actual results could differ from those estimates.

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — Continued
For the Years Ended December 31, 2000, 1999 and 1998

Financial Instruments

The carrying values of cash and cash equivalents, accounts receivable, accounts payable and accrued expenses are reasonable estimates of fair value due to the short-term nature of these financial instruments. Investments are reported at amortized cost, which approximates fair value.

Advertising Costs

Advertising costs are expensed as incurred and are included in selling, general and administrative expenses. Advertising expenses were \$270,000, \$100,000 and \$340,000 for 2000, 1999 and 1998, respectively.

Software Development Costs

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

Unamortized software and software development costs included in the Company's balance sheet were \$70,000 and \$390,000 at December 31, 2000 and 1999, respectively. Amortization expense related to capitalized software costs were \$330,000, \$330,000 and \$260,000 in 2000, 1999 and 1998, respectively. During 1999, \$30,000 of unamortized software development costs were expensed.

Research and development expenses included in selling, general and administrative expenses were \$890,000 and \$590,000 in 2000 and 1999 respectively.

Foreign Currency Translation

The assets and liabilities of the Company's foreign subsidiaries are translated into U.S. dollars at current exchange rates. Revenue and expense accounts of these operations are translated at average rates prevailing during the period. These translation adjustments are accumulated in a separate component of shareholders' equity. Foreign currency transaction gains and losses are included in determining net income (loss) when realized.

Reclassification

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

2. Notes Receivable

In September 1999, the Company loaned an officer \$44,400 as part of a relocation package. During 2000 the Company loaned an additional \$18,100 to this officer as part of the same relocation package. No repayments to the Company have been made on this loan. The loan bears interest at 5.5%, compounded monthly. Accrued but unpaid interest on this loan totaled \$3,713 and \$665 at December 31, 2000 and 1999, respectively.

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — Continued
For the Years Ended December 31, 2000, 1999 and 1998

The Company also has another employee loan outstanding of \$16,508 bearing interest at 5.5%, compounded monthly, of which \$6,114 is payable to the Company prior to December 31, 2001.

3. Short-term Investments

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

	December 31, 2000		December 31, 1999	
	Cost	Amortized Cost	Cost	Amortized Cost
U.S. Treasury securities and obligations of U.S. government agencies	\$ —	\$ —	\$ 2,336,292	\$ 2,343,391
Obligations of states and political subdivisions	1,935,500	1,978,858	—	—
U.S. corporate obligations	7,570,466	7,677,994	12,134,002	12,231,680
	<u>\$9,505,966</u>	<u>\$9,656,852</u>	<u>\$14,470,294</u>	<u>\$14,575,071</u>

4. Impairment Charges and Special Items

During 1998, the Company recorded total special items charges of \$1,998,187. The Company recorded a charge of \$1,439,762 in the first quarter of 1998 to recognize costs associated with employee severance and other special items including the March 24, 1998 termination of 29 employees pursuant to a reorganization plan announced in March 1998 and completed before the end of the second quarter of 1998. In June 1998, an additional special items charge of \$271,425 was recorded related to the closing of the Company's United Kingdom operations (including the termination of two employees) and the termination of a joint venture in the United Kingdom, and additional costs incurred in connection with the termination of the IBM and DATATRAK alliance. In September 1998, a special items charge of \$287,000 was recorded associated with the closure of two of the Company's owned Clinical Business sites, including severance related costs for two employees at these locations.

Also during 1998, the Company recorded impairment charges of \$6,056,019 related to the impairment of goodwill. Of this charge, \$1,848,307 was related to goodwill written off during the third quarter of 1998 related to the two Clinical Business locations that were closed in September of 1998 due to their poor operating performance and represented the remaining unamortized goodwill allocated to these locations at the time of their purchase in 1996. The remaining \$4,207,712 was for goodwill associated with GFI.

GFI, a subsidiary, was acquired in January 1996 for \$6.0 million with substantially all of the purchase price being allocated to goodwill. Subsequently, pursuant to SFAS 121, the Company evaluated the recoverability of the long-lived assets including intangibles of its GFI subsidiary. GFI's revenue continued to decline and its net losses continued to increase since its acquisition. In addition, the two principals responsible for the development of GFI, prior to its purchase by the Company, left the Company and a new management team was put in place. In the third quarter of 1998, after new management's efforts to effect a turn around were exhausted, and concurrent with the Company's planning process, it was determined that the possibility of recovering the recorded value of the long-lived GFI assets through a sale of GFI, exclusive of a sale of the entire Clinical Business was remote. In addition, it was determined that GFI's future undiscounted cash flows were below the carrying value of GFI's long-lived assets. Accordingly, during the third quarter of 1998, the Company adjusted the carrying value of GFI's long-lived assets to their estimated fair value of approximately \$1.6 million, resulting in a non-cash charge of \$4,207,712. The

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — Continued
For the Years Ended December 31, 2000, 1999 and 1998

estimated fair value was based on the purchase price allocated to GFI pursuant to an initial offer from West Pharmaceutical Services (“West”) to purchase the Clinical Business.

Details of the impairment charges and special items, of which asset write-offs and goodwill impairment represent non-cash charges, are as follows:

	Special Items				
	Goodwill Impairment	Asset Write-offs	Termination Benefits	Other Exit Costs	Total
Reserve at January 1, 1998			\$ —	\$2,100,000	
1998 charges:					
March 1998 corporate reorganization	\$ —	\$ —	1,194,762	245,000	\$1,439,762
June 1998:					
Termination of IBM alliance	—	—	—	126,425	126,425
Exiting of United Kingdom activities	—	27,023	18,000	99,977	145,000
	—	27,023	18,000	226,402	271,425
September 1998:					
Closure of two clinical sites	1,848,307	—	15,000	272,000	287,000
GFI goodwill impairment	4,207,712	—	—	—	—
	6,056,019	—	15,000	272,000	287,000
Total 1998 charges	<u>\$6,056,019</u>	<u>\$27,023</u>	1,227,762	743,402	<u>\$1,998,187</u>
1998 payments and adjustments:					
Termination of IBM alliance			—	2,080,300	\$2,080,300
Closing of leased facility			—	82,443	82,443
March 1998 corporate reorganization			648,934	176,155	825,089
Exiting of United Kingdom activities			18,000	50,202	68,202
Closure of two clinical sites			15,000	13,420	28,420
Total 1998 payments and adjustments			681,934	2,402,520	<u>\$3,084,454</u>
Reserve at December 31, 1998			545,828	440,882	
1999 payments and adjustments:					
Termination of IBM alliance			—	46,125	\$ 46,125
Closing of leased facility			—	111,914	111,914
March 1998 corporate reorganization			545,828	68,846	614,674
Exiting of United Kingdom activities			—	49,627	49,627
Closure of two clinical sites			—	104,097	104,097
Total 1999 payments and adjustments			545,828	380,609	<u>\$ 926,437</u>
Reserve at December 31, 1999			<u>\$ —</u>	\$ 60,273	
2000 payments and adjustments:					
Closing of leased facility				60,273	<u>\$ 60,273</u>
Reserve at December 31, 2000				<u>\$ —</u>	

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — Continued
For the Years Ended December 31, 2000, 1999 and 1998

5. Accounts Receivable

Accounts receivable consist of the following:

	December 31,	
	2000	1999
Trade accounts receivable:		
Billed	\$543,959	\$205,735
Unbilled	74,868	58,758
Total trade accounts receivable	618,827	264,593
Other	37,024	100,052
Allowance for doubtful accounts	(46,500)	(30,000)
	<u>\$609,351</u>	<u>\$334,645</u>

Included in other receivables at December 31, 1999, is \$73,000, which is due from West as final settlement on the accounts receivable that were sold on April 20, 1999 along with the Clinical Business. This amount was collected in January 2000.

Movement of the allowance for doubtful accounts is as follows:

	Year ended December 31,		
	2000	1999	1998
Balance at beginning of year	\$30,000	\$ 158,000	\$310,000
Provision (credit) for uncollectible accounts	16,500	28,000	(55,000)
Sale of Clinical Business	—	(154,000)	—
Uncollectible accounts written off	—	(2,000)	(97,000)
Balance at end of year	<u>\$46,500</u>	<u>\$ 30,000</u>	<u>\$158,000</u>

The net credit for uncollectible accounts recognized in 1998 was primarily due to favorable collection efforts in 1998 of disputed contracts, provided for in the prior year.

6. Accrued Expenses

Accrued expenses consist of the following:

	December 31,	
	2000	1999
Contract services costs	\$101,299	\$112,247
Special items (see Note 4)	—	60,273
Payroll and other employee costs	371,664	220,433
Professional fees	292,214	176,519
Income taxes payable	12,327	209,038
Other	136,610	86,059
	<u>\$914,114</u>	<u>\$864,569</u>

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — Continued
For the Years Ended December 31, 2000, 1999 and 1998

7. Income Taxes

Income tax expense consists of the following:

	Year ended December 31,		
	2000	1999	1998
Current:			
Federal	\$—	\$ 92,000	\$ —
State and local	—	292,000	80,000
	<u>\$—</u>	<u>\$384,000</u>	<u>\$80,000</u>

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

	Year ended December 31,		
	2000	1999	1998
Income taxes (benefit) at the United States statutory rate	\$(1,796,500)	\$ 3,435,200	\$(4,758,700)
Non-U.S. income tax	61,600	363,500	457,600
State and local income taxes	—	192,700	52,800
Net operating loss carryback (carryforward)	—	(1,629,300)	—
Federal alternative minimum tax	—	92,000	—
Change in valuation allowance	1,779,000	(3,804,000)	4,871,000
Allowances, accruals and other	44,100	1,733,900	(542,700)
	<u>\$ —</u>	<u>\$ 384,000</u>	<u>\$ 80,000</u>

At December 31, 2000 the Company had a net operating loss carryforward of approximately \$11.4 million, for United States income tax purposes, which will expire in the year 2020. The Company also had a net operating loss carryforward of approximately \$3.3 million, for German income tax purposes, with no expiration date. The significant components of the Company's deferred tax assets (liabilities) are as follows:

	December 31,	
	2000	1999
Deferred tax assets (liabilities):		
U.S. net operating loss carryforwards	\$ 3,871,000	\$ 2,546,000
Non-U.S. net operating loss carryforwards	1,263,000	936,000
Alternative minimum tax credit	92,000	—
Allowances and accruals	138,000	107,000
Depreciation and amortization	(70,000)	(74,000)
	<u>5,294,000</u>	<u>3,515,000</u>
Valuation allowance	(5,294,000)	(3,515,000)
Net deferred tax assets recorded	<u>\$ —</u>	<u>\$ —</u>

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — Continued
For the Years Ended December 31, 2000, 1999 and 1998

8. Operating Leases

The Company leases certain office equipment and space. Rent expense relating to these operating leases was approximately \$280,000, \$490,000 and \$1,060,000 in 2000, 1999 and 1998, respectively. Future minimum lease payments and sublease receipts for the Company under noncancelable operating leases as of December 31, 2000 are as follows:

<u>Year ending December 31,</u>	<u>Payments</u>	<u>Receipts</u>
2001	\$269,900	\$ 75,600
2002	99,300	25,700
2003	8,700	—
	<u>\$377,900</u>	<u>\$101,300</u>

9. Shareholders' Equity

Serial Preferred Shares

At December 31, 2000 and 1999, the Company had 1,000,000 Serial Preferred Shares, without par value, authorized, with none outstanding.

Treasury Shares

On August 9, 1999, the Company completed a tender offer by repurchasing 3.3 million of its Common Shares at a purchase price of \$6.00 per share. The cost of the tender offer was \$20.2 million.

10. Share Option Plans

The Company has five share option plans. At December 31, 2000, the Company had reserved 1,430,208 Common Shares for the exercise of Common Share options. Of the 1,430,208 Common Shares reserved, 305,041 have previously been issued, leaving 1,125,167 available for future exercises of Common Share options. The weighted average contractual life of all options outstanding was 7.9 years as of December 31, 2000. The range of exercise prices for all options outstanding at December 31, 2000 was \$0.15 to \$10.75.

The Amended and Restated 1994 Directors' Share Option Plan ("Director Plan") was established by the Company in July 1994. The Director Plan provided for the granting of a maximum of 11,000 options to purchase Common Shares to directors of the Company for their participation in Board of Directors' meetings. The option price per share is equal to the fair market value of a Common Share on the date of grant. All options awarded and outstanding under the Director Plan are 100% vested as of December 31, 2000. All options granted under the Director Plan expire ten years after the grant date.

The Amended and Restated 1992 Share Incentive Plan ("1992 Plan") was approved by the Company's shareholders on September 23, 1992. The 1992 Plan provided for the granting of a maximum of 481,333 options to purchase Common Shares to key employees and consultants of the Company and its affiliates. Prior to May 1995, options to purchase 316,499 Common Shares were granted at exercise prices of less than the fair market value of a Common Share on the date of grant. The Company recognized compensation expense related to these Common Share options \$5,585 in 1998. No further compensation expense will be recorded related to these Common Share

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — Continued
For the Years Ended December 31, 2000, 1999 and 1998

options. Subsequent to April 1995, all options to purchase Common Shares awarded under the 1992 Plan were granted at exercise prices that represented the fair market value of a Common Share on the date of grant. All options awarded and outstanding under the 1992 Plan are 100% vested as of December 31, 2000. All options granted under the 1992 Plan expire ten years after the grant date.

The Amended and Restated 1996 Outside Directors' Stock Option Plan, as amended ("1996 Director Plan") was established by the Company in February 1996. The 1996 Director Plan provided for the granting of a maximum of 175,000 options to purchase Common Shares to outside directors of the Company. During 1999, 70,000 Common Share options were granted at exercise prices of less than the fair market value of a Common Share on the date of grant. The Company recognized compensation expense related to these Common Share options of \$21,700 in 1999. No further compensation expense will be recorded related to these Common Share options. All other options granted under the 1996 Director Plan have been granted at exercise prices that represented the fair market value of a Common Share on the date of grant. All options awarded and outstanding under the 1996 Director Plan are 100% vested as of December 31, 2000. All options granted under the 1996 Director Plan expire ten years after the grant date.

The Amended and Restated 1996 Key Employees and Consultants Stock Option Plan ("1996 Plan") was established by the Company in February 1996. The 1996 Plan provides for the granting of a maximum of 757,667 options to purchase Common Shares to key employees and consultants of the Company and its affiliates. During 2000, 77,354 Common Share options were granted at exercise prices of less than the fair market value of a Common Share on the date of grant. The Company recognized compensation expense related to these Common Share options of \$14,514 in 2000. If all options vest, additional compensation expense of \$45,000 will be recognized through 2004. All other options granted under the 1996 Plan have been granted at exercise prices that represented the fair market value of a Common Share on the date of grant. Vesting of options awarded under the 1996 Plan is determined by the Company's Compensation Committee, as appointed by the Board of Directors, and all options granted under the 1996 Plan expire ten years after the grant date.

During 1999, the Company established the 1999 Outside Director Stock Option Plan ("1999 Plan"). The 1999 Plan provides for the granting of a maximum of 250,000 options to purchase Common Shares to outside directors of the Company. In 1999, the Company's Board of Directors approved the granting of a total of 72,500 Common Share options at exercise prices of \$3.63 and \$3.75 per share. These option grants were approved by the Company's shareholders and granted in 2000 at exercise prices of less than the fair market value of a Common Share on the date of grant. The Company recognized compensation expense related to these Common Share options of \$105,600 in 2000. No further compensation expense will be recorded related to these Common Share options. All other options granted under the 1999 Plan have been granted at exercise prices that represented the fair market value of a Common Share on the date of grant. Options fully vest one year following the grant date. All options granted under the 1999 Plan expire ten years after the grant date.

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — Continued
For the Years Ended December 31, 2000, 1999 and 1998

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

	Year ended December 31,					
	2000		1999		1998	
	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price	Options	Weighted Average Exercise Price
Outstanding at beginning of period	666,089	\$3.83	444,650	\$4.69	564,775	\$5.30
Granted	270,434	4.58	495,489	3.78	31,000	4.24
Exercised	—	—	(167,450)	3.05	(10,000)	0.21
Cancelled	(17,281)	6.33	(106,600)	8.44	(141,125)	7.31
Outstanding at end of period	919,242	\$2.78	666,089	\$3.83	444,650	\$4.69
Exercisable at end of period	354,350	\$3.20	252,600	\$4.06	274,800	\$3.26

11. Stock Based Compensation

The Company has elected to follow APB 25 and related interpretations in accounting for its employee and director stock options. As discussed below, the alternative fair value accounting provided for under Financial Accounting Standards Board Statement No. 123, “Accounting for Stock-Based Compensation” (“SFAS 123”) requires use of option valuation models that were not developed for use in valuing employee stock options. Under APB 25 compensation expense has been recognized for all options granted at less than the fair market value of the Common Shares on the date of grant.

Pro forma information regarding net income and earnings per share is required by SFAS 123, which also requires that the information be determined as if the Company has accounted for its employee stock options granted subsequent to December 31, 1994 under the fair value method of that Statement. The following assumptions were used to determine the fair value for these options using a Black-Scholes option pricing model.

	Year ended December 31		
	2000	1999	1998
Risk free interest rate	6.5%	5.5%	5.5%
Volatility factor of the expected market price of the Common Shares	0.57	0.34	0.34
Dividend yield	0.0%	0.0%	0.0%
Weighted-average expected life of the option	7 years	7 years	7 years
Weighted-average fair value per share of options granted	\$3.34	\$2.18	\$1.92

The Black-Scholes option valuation model was developed for use in estimating the fair value of traded options, which have no vesting restrictions and are fully transferable. In addition, option valuation models require the input of highly subjective assumptions including the expected stock price volatility. Because the Company’s employee stock options have characteristics significantly different from those of traded options, and because changes in the subjective input assumptions can materially affect the fair value estimate, in management’s opinion,

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — Continued
For the Years Ended December 31, 2000, 1999 and 1998

the existing models do not necessarily provide a reliable single measure of the fair value of its employee stock options.

For purposes of pro forma disclosures, the estimated value of the options is amortized to expense over the options' vesting period. The pro forma results are not necessarily indicative of what would have occurred had the Company adopted SFAS 123. The Company's pro forma information follows:

	Year ended December 31,		
	2000	1999	1998
Pro forma net income (loss)	\$(5,805,030)	\$8,899,528	\$(14,485,188)
Pro forma basic income (loss) per share	\$ (1.88)	\$ 1.81	\$ (2.48)
Pro forma diluted income (loss) per share	\$ (1.88)	\$ 1.78	\$ (2.48)

12. Retirement Savings Plan

The Company sponsors The DATATRAK International, Inc. Retirement Savings Plan (the "Plan") as defined by Section 401(k) of the Internal Revenue Code of 1986, as amended. The Plan covers substantially all employees who elect to participate. Participants may contribute up to 20% of their annual compensation into a variety of mutual fund options or Common Shares. Matching and profit sharing contributions by the Company are discretionary. The Company did not make any matching or profit sharing contributions in 2000, 1999 or 1998.

13. Segment Information

Prior to April 20, 1999, the Company operated in two principal business segments: The DATATRAK EDC Business and the Clinical Business. The Clinical Business was sold on April 20, 1999. The DATATRAK EDC Business provides EDC technology and other services to assist various clinical trial sponsors and CROs in the timely completion of clinical trials. The Clinical Business, a multi-specialty site management organization, provided Phase I through IV clinical research services and over-the-counter product services. Subsequent to April 20, 1999, the Company operates only the DATATRAK EDC Business.

The Company evaluated performance and allocated resources based on profit or loss from operations before other income and expense and income taxes. The accounting policies of the reportable segments are the same as those described in the summary of significant accounting policies. There were no intersegment sales.

The Company's reportable segments represent business units that offered different services utilized in the performance of clinical trials. The reportable segments were managed separately because they offered separate and distinct services to customers in the clinical research industry.

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — Continued
For the Years Ended December 31, 2000, 1999 and 1998

Information on the Company's business segments is as follows:

Year ended December 31,	DATATRAK EDC Business	Clinical Business	Total
Revenue:			
2000	\$ 1,993,785	\$ —	\$ 1,933,785
1999	900,388	4,910,777	5,811,165
1998	131,752	13,094,326	13,226,078
Impairment charge:			
2000	—	—	—
1999	—	—	—
1998	—	6,056,019	6,056,019
Special items:			
2000	—	—	—
1999	—	—	—
1998	753,214	1,244,973	1,998,187
Depreciation and amortization:			
2000	867,484	—	867,484
1999	670,630	129,865	800,495
1998	469,872	685,238	1,155,110
Income (loss) from operations:			
2000	(6,195,900)	—	(6,195,900)
1999	(4,917,535)	294,493	(4,623,042)
1998	(5,625,728)	(9,837,447)	(15,463,175)
Expenditures for long-lived assets:			
2000	1,029,494	—	1,029,494
1999	737,717	8,717	746,434
1998	1,405,925	240,505	1,646,430
Assets at December 31,			
2000	14,486,000	—	14,486,000
1999	19,483,393	—	19,483,393

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — Continued
For the Years Ended December 31, 2000, 1999 and 1998

Enterprise-Wide Disclosures

Geographic Information

Year ended December 31,	United States	United Kingdom	Germany	Total
Revenue:				
2000	\$ 1,541,921	\$ —	\$451,864	\$ 1,993,785
1999	5,598,946	—	212,219	5,811,165
1998	13,093,095	1,231	131,752	13,226,078
Assets at December 31,				
2000	13,649,298	—	836,702	14,486,000
1999	19,199,049	—	284,344	19,483,393

Major Customers — During the year ended December 31, 2000, the DATATRAK EDC Business recorded revenue of approximately \$1.0 million and \$550,000 from two separate customers. During 1999 and 1998, the DATATRAK EDC Business had no customers that accounted for 10% or more of the Company's total revenue.

During 1999, the Clinical Business recorded revenue of approximately \$1.0 million from one customer. During 1998, the Clinical Business recorded revenue of approximately \$1.9 million and \$1.7 million from two separate customers.

14. Net Income (Loss) Per Share

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

	Year Ended December 31,		
	2000	1999	1998
Net income (loss) used in the calculation of basic and diluted earnings per share	<u>\$(5,283,747)</u>	<u>\$9,719,542</u>	<u>\$(14,076,222)</u>
Denominator for basic net income (loss) per share - weighted average Common Shares outstanding	3,290,322	5,208,535	6,421,820
Effect of dilutive Common Share options	—	84,951	—
Denominator for diluted net income (loss) per share	<u>3,290,322</u>	<u>5,293,486</u>	<u>6,421,820</u>
Basic net income (loss) per share	<u>\$ (1.61)</u>	<u>\$ 1.87</u>	<u>\$ (2.19)</u>
Diluted net income (loss) per share	<u>\$ (1.61)</u>	<u>\$ 1.84</u>	<u>\$ (2.19)</u>
Common Share options excluded from the computation of diluted net income (loss) per share because they would have an antidilutive effect on net income (loss) per share	<u>919,242</u>	<u>212,576</u>	<u>444,650</u>

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — Continued
For the Years Ended December 31, 2000, 1999 and 1998

15. Quarterly Data (Unaudited)

Selected quarterly data is as follows (in thousands):

Year Ended December 31, 2000				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenue	\$ 497	\$ 435	\$ 517	\$ 545
Gross profit	146	68	41	142
Loss from operations	(1,301)	(1,641)	(1,578)	(1,676)
Net loss	(1,055)	(1,412)	(1,346)	(1,471)
Net loss per share: basic	(0.32)	(0.43)	(0.41)	(0.45)
Net loss per share: diluted	(0.32)	(0.43)	(0.41)	(0.45)

Year Ended December 31, 1999				
	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Revenue	\$ 4,180	\$ 924	\$ 172	\$ 535
Gross profit	1,556	283	39	170
Loss from operations	(1,236)	(934)	(1,193)	(1,260)
Net income (loss)	(1,109)	11,738	(939)	30
Net income (loss) per share: basic	(0.17)	1.82	(0.20)	0.01
Net income (loss) per share: diluted	(0.17)	1.79	(0.20)	0.01

During the fourth quarter of 2000, the Company completed a study of employee and other costs involved with research and development activities. Such research and development costs were reclassified from direct costs to selling, general and administrative expenses, with no effect on reported net income. The impact of the reclassification was to increase gross profit by approximately \$130,000 for each of three previously reported quarters in the year ended December 31, 2000. The impact of the reclassification was to increase previously reported gross profit by approximately \$40,000 for each of the first three quarters in 1999, and to increase previously reported gross profit by approximately \$130,000 for the quarter ended December 31, 1999.

During the second quarter of 1999, the Company sold its Clinical Business to West, resulting in a gain of \$12.2 million. During the fourth quarter of 1999, the Company recorded \$1.3 million of other income as a result of a favorable lawsuit settlement.

Exhibit Index

Exhibit No.	Description	Page
3.1	Fifth Amended and Restated Articles of Incorporation	(B)
3.2	Form of Certificate of Amendment to the Fifth Amended and Restated Articles of Incorporation	(F)
3.3	Form of Certificate of Amendment to the Fifth Amended and Restated Articles of Incorporation	(G)
3.3	Third Amended and Restated Code of Regulations	(B)
4.1	Specimen Certificate of the Company’s Common Shares, without par value	(H)
4.2	Second Amended and Restated Registration Agreement, dated July 15,1994, as amended on June 1, 1995 and February 5, 1996	(A)
10.1	Amended and Restated 1994 Directors’ Share Option Plan*	(C)
10.2	Amended and Restated 1996 Outside Directors’ Stock Option Plan*	(C)
10.3	Amendment No. 2 to the Amended and Restated 1996 Outside Directors’ Stock Option Plan*	(F)
10.4	Amended and Restated 1992 Share Incentive Plan*	(C)
10.5	Amended and Restated 1996 Key Employees’ and Consultants Stock Option Plan*	(C)
10.7	Form of Indemnification Agreement*	(A)
10.8	Employment Agreement between the Company and Jeffrey A. Green, dated February 5,2001*	
10.9	Employment Agreement between the Company and Terry C. Black, dated February 5,2001*	
10.10	Separation Agreement between the Company and Terry C. Black, dated December 22, 1998*	(E)
10.11	Employment Agreement between the Company and Marc J. Shlaes dated July 2, 1998*	(H)
10.12	Employment Agreement between the Company and Wolfgang Summa, dated December 29, 2000*	
10.13	DATATRAK International, Inc. Retirement Savings Plan*	(D)
21.1	Subsidiaries of the Company	

Exhibit Index

Exhibit No.	Description	Page
23.1	Consent of Ernst & Young LLP	
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*	Management compensatory plan or arrangement.	
(A)	Incorporated herein by reference to the appropriate exhibit to the Company’s Registration Statement on Form S-1 (Registration statement No. 333-2140).	
(B)	Incorporated herein by reference to the appropriate exhibit to the Company’s Form 10-Q for the quarterly period ended June 30, 1996 (Commission file No. 000-20699).	
(C)	Incorporated herein by reference to the appropriate exhibit to the Company’s Registration Statement on Form S-8 (Registration statement No. 333-16061).	
(D)	Incorporated herein by reference to the appropriate exhibit to the Company’s Registration Statement on Form S-8 (Registration statement No. 333-26251).	
(E)	Incorporated herein by reference to the appropriate exhibit to the Company’s Form 10-K for the year ended December 31, 1998 (Commission file No. 000-20699).	
(F)	Incorporated herein by reference to the appropriate exhibit to the Company’s Schedule 14A dated March 17, 1999 (Commission File No. 000-20699).	
(G)	Incorporated herein by reference to the appropriate exhibit to the Company’s Schedule 14A dated August 25, 1999 (Commission File No. 000-20699).	
(H)	Incorporated herein by reference to the appropriate exhibit to the Company’s Form 10-K for the year ended December 31, 2000 (Commission file No. 000-20699).	