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Securities and Exchange Commission
Washington, D.C. 20549

Form 10-Q

Quarterly Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

For the Quarterly Period Ended March 31, 2001

Commission file number 000-20699

DATATRAK International, Inc.

(Exact name of registrant as specified in its charter)

<u>Ohio</u> (State or other jurisdiction of incorporation or organization)	<u>34-1685364</u> (I.R.S. Employer Identification No.)
<u>20600 Chagrin Boulevard Cleveland, Ohio</u> (Address of principal executive offices)	<u>44122</u> (Zip Code)
<u>(216) 921-6505</u> (Registrants telephone number, including area code)	
<u>(Former name, former address and former fiscal year, if changed since last report)</u>	

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.
 X Yes No

Indicate the number of shares outstanding of each of the issuer’s classes of common stock, as of the latest practical date.

The number of Common Shares, without par value, outstanding as of April 30, 2001 was 3,290,322.

Part I. Financial Information

Item 1 — Financial Statements

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

	March 31, 2001	(Note A) December 31, 2000
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,010,667	\$ 2,383,244
Short-term investments	8,207,219	9,656,852
Accounts receivable, less allowances	708,989	609,351
Prepaid expenses and other current assets	327,283	377,212
Total current assets	11,254,158	13,026,659
Property and equipment, at cost net of accumulated depreciation and amortization	1,906,111	1,374,352
Other assets	67,947	84,989
Total assets	<u>\$ 13,228,216</u>	<u>\$ 14,486,000</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 230,808	\$ 129,038
Current portion of capital lease obligation	123,073	—
Accrued expenses	739,313	914,114
Deferred revenue	340,986	338,879
Total current liabilities	1,434,180	1,382,031
Capital lease obligation, less current portion	260,238	—
Shareholders' equity:		
Serial preferred shares, without par value, 1,000,000 shares authorized, none issued	—	—
Common shares, without par value, authorized 15,000,000 shares; issued 6,590,322 shares as of December 31, 2000 and March 31, 2001; outstanding 3,290,322 shares as of December 31, 2000 and March 31, 2001	50,360,360	50,356,667
Accumulated deficit	(18,578,059)	(16,987,206)
Treasury shares, 3,300,000 shares at cost	(20,188,308)	(20,188,308)
Foreign currency translation	(60,195)	(77,184)
Total shareholders' equity	11,533,798	13,103,969
Total liabilities and shareholders' equity	<u>\$ 13,228,216</u>	<u>\$ 14,486,000</u>

Note A: The balance sheet at December 31, 2000 has been derived from the audited consolidated financial statements at that date, but does not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements.

See notes to condensed consolidated financial statements.

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	Three Months Ended March 31,	
	2001	2000
Revenue	\$ 673,113	\$ 497,342
Direct costs	429,618	351,335
Gross profit	243,495	146,007
Selling, general and administrative expenses	1,742,634	1,259,466
Depreciation and amortization	231,001	187,480
Loss from operations	(1,730,140)	(1,300,939)
Other income (expense):		
Interest income	162,207	237,944
Other income (expense)	(22,920)	7,785
Net loss	<u>\$(1,590,853)</u>	<u>\$(1,055,210)</u>
Basic and diluted net loss per share	<u>\$ (0.48)</u>	<u>\$ (0.32)</u>
Weighted average common shares outstanding	<u>3,290,322</u>	<u>3,290,322</u>

See notes to condensed consolidated financial statements.

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(Unaudited)

	Three Months Ended March 31,	
	2001	2000
Operating Activities		
Net loss	\$(1,590,853)	\$ (1,055,210)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	231,001	187,480
Other	(129,027)	(200,194)
Changes in operating assets and liabilities:		
Accounts receivable	(104,138)	(247,115)
Accounts payable and accrued expenses	(73,025)	(170,778)
Other	53,352	16,952
Net cash used in operating activities	(1,612,690)	(1,468,865)
Investing Activities		
Purchases of property and equipment	(367,608)	(281,890)
Maturities of short term investments	8,980,000	17,029,000
Purchases of short term investments	(7,393,148)	(16,176,492)
Net cash provided by investing activities	1,219,244	570,618
Financing Activities		
Payments under capital lease obligation	(9,889)	—
Repayment (issuance) of notes receivable	15,726	(6,540)
Net cash provided by (used in) financing activities	5,837	(6,540)
Effect of exchange rate on cash	15,032	(61,233)
Decrease in cash and cash equivalents	(372,577)	(966,020)
Cash and cash equivalents at beginning of period	2,383,244	2,961,403
Cash and cash equivalents at end of period	<u>\$ 2,010,667</u>	<u>\$ 1,995,383</u>

See notes to condensed consolidated financial statements.

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2001
(Unaudited)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of DATATRAK International, Inc. and subsidiaries (“DATATRAK” or the “Company”) have been prepared in accordance with accounting principles generally accepted in the United States for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by accounting principles generally accepted in the United States for complete financial statements. In the opinion of management, all adjustments (consisting of normal recurring accruals) considered necessary for a fair presentation have been included. Operating results for the three-month period ended March 31, 2001 are not necessarily indicative of the results that may be expected for the year ending December 31, 2001. For further information, refer to the consolidated financial statements and footnotes thereto included in the Company’s Form 10-K for the year ended December 31, 2000 (File No. 000-20699).

The preparation of financial statements in conformity with accounting principles generally accepted in the United States 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.

2. Net Loss per Share

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

	Three Months Ended March 31,	
	2001	2000
Net loss used in the calculation of basic and diluted earnings per share	<u>\$(1,590,853)</u>	<u>\$(1,055,210)</u>
Denominator for basic and diluted net loss per share – weighted average Common Shares outstanding	<u>3,290,322</u>	<u>3,290,322</u>
Basic and diluted net loss per share	<u>\$ (0.48)</u>	<u>\$ (0.32)</u>
Common Share options excluded from the computation of diluted net loss per share because they would have an antidilutive effect on net loss per share	<u>931,658</u>	<u>666,089</u>

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
March 31, 2001
(Unaudited)

3. Capital Lease Obligation

During March 2001, the Company entered into an agreement with an unaffiliated third party to lease certain computer equipment. The lease has been recorded as a capital lease. Terms of the lease agreement require the Company to maintain a restricted cash balance equal to the outstanding balance payable on the lease (\$383,311 at March 31, 2001). Future minimum lease payments under the capital lease obligation as of March 31, 2001 are as follows:

<u>Twelve months ending March 31,</u>	
2002	\$145,089
2003	145,089
2004	<u>132,997</u>
	423,175
Less amounts representing interest	<u>39,864</u>
	<u><u>\$383,311</u></u>

4. Comprehensive loss

The following table sets forth comprehensive loss.

	<u>Three Months Ended March 31,</u>	
	<u>2001</u>	<u>2000</u>
Net loss	\$(1,590,853)	\$(1,055,210)
Foreign currency translation	<u>16,989</u>	<u>(35,214)</u>
Comprehensive loss	<u><u>\$(1,573,864)</u></u>	<u><u>\$(1,090,424)</u></u>

5. Reclassification

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

Item 2. Management’s Discussion and Analysis of Results of Operations and Financial Condition

The information set forth and discussed below for the three months ended March 31, 2001 is derived from the Condensed Consolidated Financial Statements included elsewhere herein. The financial information set forth and discussed below is unaudited, but in the opinion of management, reflects all adjustments (consisting of normal recurring accruals) necessary for a fair presentation of such information. The Company’s results of operations for a particular quarter may not be indicative of results expected during the other quarters or for the entire year.

General

DATATRAK is an application service provider (“ASP”) that uses the software known as DATATRAK EDC™ to provide 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. Approximately 77% of the Company’s assets, or approximately \$10.2 million, are held in cash, cash equivalents and short-term investments. The Company has recognized minimal revenue and has experienced significant losses and negative cash flow from operations since commencing EDC operations in 1997. The Company is continuing to develop and commercialize the DATATRAK EDC™ software and anticipates that its operating results will fluctuate significantly from period to period. There can be no assurance of the Company’s long-term future prospects.

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 several months to several years. 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 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.

Since its purchase of the DATATRAK EDC™ software in January 1998, DATATRAK has recorded revenue related to a small number of contracts. At March 31, 2001, DATATRAK’s backlog was \$5.0 million. Due to DATATRAK’s early stage of development and its low level of backlog, there can be no assurance as to its future levels of revenue.

Results of Operations

Three months ended March 31, 2001 compared with three months ended March 31, 2000

Revenue for the three months ended March 31, 2001 increased 34.0% to \$670,000 as compared to \$500,000 for the three months ended March 31, 2000. The increase was the result of an increase in the number of clinical trials using the DATATRAK EDC™ software. Twice as many clinical trails used DATATRAK EDC™ during the three months ended March 31, 2001 as compared to the three months ended March 31, 2000.

Direct costs of revenue, mainly personnel costs, were \$430,000 and \$350,000 during the three months ended March 31, 2001 and 2000, respectively. The 22.9% increase in direct costs was mainly the result of increased personnel costs of \$50,000 caused by additional employees. The remaining increase was due to additional contract costs related to the increased usage of the DATATRAK EDC™ software.

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. SG&A expenses increased by 30.8% to \$1.7 million from \$1.3 million for the three months ended March 31, 2001 and 2000, respectively. Of the increase, \$380,000 was due to increased personnel costs, which were partially offset by a \$110,000 decrease in consulting costs. The remaining increase was caused by an increase in other SG&A expenses associated with the Company’s development of and marketing of the DATATRAK EDC™ software.

Depreciation and amortization expense increased to \$230,000 during the three months ended March 31, 2001 from \$190,000 during the three months ended March 31, 2000. The increase was the result of depreciating capital expenditures associated with the building of DATATRAK’s information technology infrastructure.

Other income decreased to \$140,000 during the three months ended March 31, 2001 from \$250,000 during the three months ended March 31, 2000. Other income includes interest income which decreased \$80,000 for the three months ended March 31, 2001 compared to March 31, 2000, due to the Company’s use of cash to fund its operating losses and other working capital needs.

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.

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 \$710,000 at March 31, 2001 and \$610,000 at December 31, 2000. Deferred revenue was \$340,000 at both March 31, 2001 and December 31, 2000.

Cash and cash equivalents decreased \$370,000 during the three months ended March 31, 2001. This was the result of \$1.2 million provided by investing and financing activities, offset by \$1.6 million used in operating activities. Investing activities included net proceeds of \$1.6 million from purchases and maturities of short-term investments offset by \$370,000 used to purchase property and equipment. A capital lease obligation of \$390,000 is excluded from financing and investing activities on the Condensed Consolidated Statement of Cash Flows, entered into during the three months ended March 31, 2001. Cash used for operating activities resulted from the funding of net operating losses and other working capital needs.

At March 31, 2001, the Company had working capital of \$9.8 million, and its cash, cash equivalents and short-term investments totaled \$10.2 million. The Company’s working capital decreased

by \$1.8 million since December 31, 2000. The decrease was primarily the result of the \$1.8 million decrease in 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 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 16% of the Company's revenue for the three months ended March 31, 2001 was earned in Germany. The Company manages its risk to foreign currency exchange rates by maintaining foreign currency bank accounts in currencies 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 Form 10-Q, other SEC filings or written materials or orally by the Company or its representatives may constitute forward-looking statements that are based on management’s current beliefs, estimates and assumptions concerning the operations, future results and prospects of the Company 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. Factors that may cause actual results to differ materially from those in the forward-looking statements include the ability of the Company to absorb corporate overhead and other fixed costs in order to successfully market the DATATRAK EDC™ software; the development and fluctuations in the market for electronic data capture technology; the degree of the Company’s success in obtaining new contracts; the timing of payments from customers and the timing of clinical trial sponsor decisions to conduct new clinical trials or cancel or delay ongoing trials; dependence on key personnel; governmental regulation; the early stage of the Company’s ASP operations; and general economic conditions such as the rate of employment, inflation, interest rates and the condition of capital markets. This list of factors is not exclusive. In addition, the Company’s success depends on the outcome of various strategic initiatives it has undertaken, all of which are based on assumptions made by the Company concerning trends in the clinical research market and the health care industry.

Item 3. 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 short-term investments and has business transactions in German Deutschmarks.

Part II. Other Information

Item 1.	Legal Proceedings None.
Item 2.	Changes in Securities and Use of Proceeds None.
Item 3.	Defaults Upon Senior Securities None.
Item 4.	Submission of Matters to a Vote of Security Holders None.
Item 5.	Other Information None.

Item 6.

Exhibits and Reports on Form 8-K

(a) Exhibits

See the Exhibit Index at page E — 1 of this Form 10 — Q.

(b) Reports on Form 8-K

No reports were filed on form 8-K during the three months ended March 31, 2001.

SIGNATURES

Pursuant to the requirements 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.
Registrant

Date: 5/15/01 /s/ Jeffrey A. Green
Jeffrey A. Green,
President and Chief Executive Officer and a Director
(Principal Executive Officer)

Date: 5/15/01 /s/ Terry C. Black
Terry C. Black,
Vice President of Finance, Chief Financial Officer,
Treasurer and Assistant Secretary
(Principal Financial Officer)

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>	<u>Page</u>
4.1	Specimen Certificate of the Company’s Common Shares, without par value	(B)
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)
10.6	Amendment No. 2 to the Amended and Restated 1996 Key Employees’ and Consultants Stock Option Plan*	(G)
10.7	Form of Indemnification Agreement*	(A)
10.8	Employment Agreement between the Company and Jeffrey A. Green, dated February 5, 2001*	(H)
10.9	Employment Agreement between the Company and Terry C. Black, dated February 5, 2001*	(H)
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*	(B)
10.12	Employment Agreement between the Company and Wolfgang Summa, dated December 29, 2000*	(H)
10.13	DATATRAK International, Inc. Retirement Savings Plan*	(D)
10.14	1999 Outside Director Stock Option Plan*	(G)
15.1	Independent Accountants’ Review Report	
15.2	Acknowledgement of Ernst & Young LLP	

* Management compensatory plan or arrangement.

Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>	<u>Page</u>
(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-K for the year ended December 31, 1999 (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 May 3, 2000 (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).	