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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 September 30, 2000

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) |

(216) 921-6505

(Registrants telephone number, including area code)

(Former name, former address and former fiscal year, if changed since last report)

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 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 October 31, 2000 was 3,290,322.

Part 1. Financial Information
Item 1- Financial Statements

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS

| | (Unaudited) September 30, 2000 | (Note A) December 31, 1999 |
|---|--------------------------------------|----------------------------------|
| ASSETS | | |
| Current assets: | | |
| Cash and cash equivalents | \$ 2,610,320 | \$ 2,961,403 |
| Short-term investments | 10,577,170 | 14,575,071 |
| Accounts receivable, less allowances | 558,196 | 334,645 |
| Prepaid expenses and other current assets | 332,016 | 289,016 |
| Total current assets | 14,077,702 | 18,160,135 |
| Property and equipment, at cost net of accumulated depreciation and amortization | 1,328,053 | 1,257,558 |
| Other assets | 79,176 | 65,700 |
| Total assets | \$ 15,484,931 | \$ 19,483,393 |
| LIABILITIES AND SHAREHOLDERS' EQUITY | | |
| Current liabilities: | | |
| Accounts payable | \$ 201,178 | \$ 281,867 |
| Accrued expenses | 735,111 | 864,569 |
| Deferred revenue | 13,502 | 30,960 |
| Total current liabilities | 949,791 | 1,177,396 |
| Shareholders' equity: | | |
| Foreign currency translation | (112,705) | (38,789) |
| 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, 1999 and September 30, 2000; outstanding 3,290,322 shares as of December 31, 1999 and September 30, 2000 | 50,353,066 | 50,236,553 |
| Accumulated deficit | (15,516,913) | (11,703,459) |
| Treasury shares, 3,300,000 shares at cost | (20,188,308) | (20,188,308) |
| Total shareholders' equity | 14,535,140 | 18,305,997 |
| Total liabilities and shareholders' equity | \$ 15,484,931 | \$ 19,483,393 |

Note A: The balance sheet at December 31, 1999 has been derived from the audited consolidated financial statements at that date, but does not include all of the information and footnotes required by generally accepted accounting principles 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 September 30, | | Nine Months Ended September 30, | |
|--|---|---------------------|--|---------------------|
| | 2000 | 1999 | 2000 | 1999 |
| Revenue | \$ 517,491 | \$ 172,887 | \$ 1,449,413 | \$ 5,276,496 |
| Direct costs | 619,122 | 202,052 | 1,578,474 | 3,531,977 |
| Gross profit (loss) | (101,631) | (29,165) | (129,061) | 1,744,519 |
| Selling, general and administrative expenses | 1,255,395 | 983,477 | 3,764,413 | 4,496,853 |
| Depreciation and amortization | 221,204 | 180,957 | 627,134 | 611,083 |
| Loss from operations | (1,578,230) | (1,193,599) | (4,520,608) | (3,363,417) |
| Other income (expense): | | | | |
| Interest income | 222,409 | 331,901 | 687,543 | 1,081,927 |
| Other income (expense) | 9,402 | (1,861) | 19,611 | (67,633) |
| Gain on sale of clinical business | — | — | — | 12,154,827 |
| Income (loss) before income taxes | (1,346,419) | (863,559) | (3,813,454) | 9,805,704 |
| Income tax expense | — | 76,000 | — | 116,000 |
| Net income (loss) | <u>\$(1,346,419)</u> | <u>\$ (939,559)</u> | <u>\$(3,813,454)</u> | <u>\$ 9,689,704</u> |
| Net income (loss) per share: | | | | |
| Basic: | | | | |
| Net income (loss) per share | <u>\$ (0.41)</u> | <u>\$ (0.20)</u> | <u>\$ (1.16)</u> | <u>\$ 1.65</u> |
| Weighted average shares outstanding | <u>3,290,322</u> | <u>4,699,987</u> | <u>3,290,322</u> | <u>5,854,966</u> |
| Diluted: | | | | |
| Net income (loss) per share | <u>\$ (0.41)</u> | <u>\$ (0.20)</u> | <u>\$ (1.16)</u> | <u>\$ 1.63</u> |
| Weighted average shares outstanding | <u>3,290,322</u> | <u>4,699,987</u> | <u>3,290,322</u> | <u>5,948,356</u> |

See notes to condensed consolidated financial statements.

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

(Unaudited)

| | Nine Months Ended September 30, | |
|--|---------------------------------|---------------------|
| | 2000 | 1999 |
| Operating Activities | | |
| Net income (loss) | \$ (3,813,454) | \$ 9,689,704 |
| Adjustments to reconcile net income (loss) to net cash used in operating activities: | | |
| Depreciation and amortization | 627,134 | 611,083 |
| Gain on sale of clinical business | — | (12,154,827) |
| Other | (419,779) | (804,242) |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (235,551) | (435,367) |
| Accounts payable and accrued expenses | (210,147) | (2,356,411) |
| Other | (65,996) | (313,857) |
| Net cash used in operating activities | (4,117,793) | (5,763,917) |
| Investing activities | | |
| Purchases of property and equipment | (745,431) | (522,396) |
| Sale of business (net of cash sold) | — | 15,601,184 |
| Maturities of short term investments | 40,098,000 | 223,334,142 |
| Purchases of short term investments | (35,518,930) | (214,463,742) |
| Net cash provided by investing activities | 3,833,639 | 23,949,188 |
| Financing activities | | |
| Issuance of notes receivable | (7,938) | (62,400) |
| Purchase of treasury shares | — | (20,144,856) |
| Net proceeds from issuance of common shares | — | 510,111 |
| Net cash used in financing activities | (7,938) | (19,697,145) |
| Effect of exchange rate on cash | (58,991) | 87,938 |
| Decrease in cash and cash equivalents | (351,083) | (1,423,936) |
| Cash and cash equivalents at beginning of period | 2,961,403 | 4,072,586 |
| Cash and cash equivalents at end of period | \$ 2,610,320 | \$ 2,648,650 |

See notes to condensed consolidated financial statements.

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

September 30, 2000
(Unaudited)

1. Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of DATATRAK International, Inc. and subsidiaries (the “Company”) have been prepared in accordance with generally accepted accounting principles 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 generally accepted accounting principles 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 and nine month periods ended September 30, 2000 are not necessarily indicative of the results that may be expected for the year ending December 31, 2000. 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, 1999 (File No. 000-20699).

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.

2. Net Loss per Share

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|-------------------------------------|---------------------|------------------------------------|--------------------|
| | 2000 | 1999 | 2000 | 1999 |
| Net income (loss) used in the calculation of basic and diluted net income (loss) per share | <u>\$(1,346,419)</u> | <u>\$ (939,559)</u> | <u>\$(3,813,454)</u> | <u>\$9,689,704</u> |
| Denominator for basic net income (loss) per share — weighted average Common Shares outstanding | 3,290,322 | 4,699,987 | 3,290,322 | 5,854,966 |
| Effect of dilutive Common Share options and Warrants | <u>—</u> | <u>—</u> | <u>—</u> | <u>93,390</u> |
| Denominator for diluted net income (loss) per share | <u>3,290,322</u> | <u>4,699,987</u> | <u>3,290,322</u> | <u>5,948,356</u> |
| Basic net income (loss) per share | <u>\$ (0.41)</u> | <u>\$ (0.20)</u> | <u>\$ (1.16)</u> | <u>\$ 1.65</u> |
| Diluted net income (loss) per share | <u>\$ (0.41)</u> | <u>\$ (0.20)</u> | <u>\$ (1.16)</u> | <u>\$ 1.63</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>881,820</u> | <u>297,600</u> | <u>881,820</u> | <u>94,659</u> |

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2000
(Unaudited)

3. Segment Disclosures and Related Information

The Company currently operates one business segment: the DATATRAK EDC Business. The DATATRAK EDC Business is an Application Service Provider (“ASP”) that provides electronic data capture (“EDC”) technology and other services to assist its customers in the timely completion of clinical trials. Prior to April 20, 1999, the Company also operated the Clinical Business, which provided Phase I through IV clinical research services and over-the-counter product services. The Clinical Business was sold on April 20, 1999, and the Company no longer operates that business.

Historically, prior to the sale of the Clinical 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 were the same as those described in the summary of significant accounting policies.

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

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

| Three Months ended September 30, | DATATRAK EDC Business | Clinical Business | Total |
|---|----------------------------------|------------------------------|--------------|
| Revenue: | | | |
| 2000 | \$517,491 | \$ --- | \$ 517,491 |
| 1999 | 172,887 | --- | 172,887 |
| Loss from operations: | | | |
| 2000 | (1,578,230) | --- | (1,578,230) |
| 1999 | (1,193,599) | --- | (1,193,599) |
| Nine Months ended September 30, | | | |
| Revenue: | | | |
| 2000 | 1,449,413 | --- | 1,449,413 |
| 1999 | 365,719 | 4,910,777 | 5,276,496 |
| Income (loss) from operations: | | | |
| 2000 | (4,520,608) | --- | (4,520,608) |
| 1999 | (3,657,910) | 294,493 | (3,363,417) |

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2000
(Unaudited)

4. Comprehensive Income (loss)

The following table sets forth comprehensive income (loss).

| | Nine Months Ended September 30, | |
|------------------------------|--|--------------------|
| | 2000 | 1999 |
| Net income (loss) | \$(3,813,454) | \$9,689,704 |
| Foreign currency translation | (73,916) | 30,926 |
| Comprehensive income (loss) | <u>\$(3,887,370)</u> | <u>\$9,720,630</u> |

5. Recently Issued Accounting Standards

In December, 1999, SAB No. 101 “Revenue Recognition in Financial Statements” was issued. SAB No. 101 provides clarification in applying generally accepted accounting principles to revenue recognition in financial statements. The Company must adopt SAB No. 101 by December 31, 2000; adoption of this statement is not expected to have a material effect on the earnings or the financial position of the Company.

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

The information set forth and discussed below for the three and nine month periods ended September 30, 2000 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

The Company’s DATATRAK EDC Business is an ASP that uses the software known as DATATRAK EDC™ to provide 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. The DATATRAK EDC Business is the sole source of the Company’s revenue and along with corporate overhead is the sole draw on the Company’s working capital. Approximately 85% of the Company’s assets, or approximately \$13.2 million, are held in cash, cash equivalents and short-term investments. The DATATRAK EDC Business has recognized a small amount of revenue to date and has experienced significant losses and negative cash flow from operations since its inception in 1997. The Company is continuing to develop and commercialize the DATATRAK EDC Business and anticipates that its operating results will fluctuate significantly from period to period. The Company’s future success is dependent on market acceptance of EDC in general, and acceptance of DATATRAK EDC™ specifically.

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 six to thirty-six 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. 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 September 30, 2000, DATATRAK’s backlog was \$1.6 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 — DATATRAK EDC Business

The following tables set forth, for the periods indicated, certain items from the Company’s Consolidated Statements of Operations, expressed in thousands, for the Company’s DATATRAK EDC Business.

| | Three Months ended | | Nine Months ended | |
|--|-----------------------|-----------------------|-----------------------|-----------------------|
| | September 30, 2000 | September 30, 1999 | September 30, 2000 | September 30, 1999 |
| Revenue | \$ 517 | \$ 173 | \$ 1,449 | \$ 366 |
| Direct costs | 619 | 202 | 1,578 | 536 |
| Gross profit (loss) | (102) | (29) | (129) | (170) |
| Selling, general and administrative expenses | 1,255 | 984 | 3,764 | 3,007 |
| Depreciation and amortization | 221 | 181 | 627 | 481 |
| Loss from operations | (1,578) | (1,194) | (4,520) | (3,658) |
| Other income (expense) | 232 | 330 | 707 | 13,169 |
| Income (loss) before income taxes | (1,346) | (864) | (3,813) | 9,511 |
| Income tax expense | — | 76 | — | 116 |
| Net income (loss) | <u>\$(1,346)</u> | <u>\$ (940)</u> | <u>\$(3,813)</u> | <u>\$ 9,395</u> |

Three months ended September 30, 2000 compared with three months ended September 30, 1999

Revenue for the three months ended September 30, 2000 increased by 188.9% to \$520,000 as compared to \$180,000 for the three months ended September 30, 1999. The increase was the result of an increase in the number of clinical trials using the DATATRAK EDC™ software and related services.

Direct costs of revenue, mainly personnel costs, were \$620,000 and \$200,000 during the three months ended September 30, 2000 and 1999, respectively. The 210.0% increase in direct costs was mainly the result of increased personnel costs of \$210,000 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 32.7% from \$980,000 to \$1.3 million for the three months ended September 30, 1999 and 2000, respectively. The increase was primarily due to personnel and other costs, associated with the Company’s development of and marketing of the DATATRAK EDC Business.

Depreciation and amortization expense increased from \$180,000 during the three months ended September 30, 1999 to \$220,000 during the three months ended September 30, 2000. The increase was the result of depreciating capital expenditures associated with the building of DATATRAK’s information technology infrastructure.

Interest income, which is included in other income, decreased \$110,000 for the three months ended September 30, 2000 compared to September 30, 1999, due to the Company’s use of cash to fund its repurchase of Common Shares, operating losses and other working capital needs.

Nine months ended September 30, 2000 compared with nine months ended September 30, 1999

Revenue for the nine months ended September 30, 2000 increased by 278.4% to \$1.4 million as compared to \$370,000 for the nine months ended September 30, 1999. The increase was the result of an increase in the number of clinical trials using the DATATRAK EDC™ software and related services.

Direct costs of revenue, mainly personnel costs, were \$1.6 million and \$540,000 during the nine months ended September 30, 2000 and 1999, respectively. The 196.3% increase in direct costs was mainly the result of increased personnel costs of \$590,000 caused by additional employees. The remaining increase was due to additional contract costs related to the increased usage of the DATATRAK EDC™ software.

SG&A expenses increased by 26.7% from \$3.0 million to \$3.8 million for the nine months ended September 30, 1999 and 2000, respectively. Expenses for 1999 included a one-time expense of \$350,000 associated with services provided by an outside consultant to assess the market potential of the DATATRAK EDC™ software. Expenses for 2000 include 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. The increase for normal recurring SG&A expenses was primarily due to increased personnel and other costs, associated with the Company's increase in infrastructure for the development of and marketing of the DATATRAK EDC Business.

Depreciation and amortization expense increased from \$480,000 during the nine months ended September 30, 1999 to \$630,000 during the nine months ended September 30, 2000. The increase was the result of depreciating capital expenditures associated with the building of DATATRAK's information technology infrastructure.

During the nine months ended September 30, 1999, a \$12.2 million gain was recorded related to the sale of the Clinical Business. Other income also includes interest income which decreased \$390,000 for the nine months ended September 30, 2000 compared to September 30, 1999, 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 for the nine months ended September 30, 1999 was \$120,000. This expense is primarily result of federal alternative minimum taxes and state taxes incurred related to the gain associated with the sale of the Company's Clinical Business.

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 \$560,000 at September 30, 2000 and \$330,000 at December 31, 1999. Deferred revenue was \$14,000 at September 30, 2000 and \$31,000 at December 31, 1999.

Cash and cash equivalents decreased \$350,000 during the nine months ended September 30, 2000. This was the result of \$3.8 million provided by investing and financing activities, offset by \$4.1 million used in operating activities. Investing activities included net proceeds of \$4.6 million from purchases and maturities of short-term investments offset by \$750,000 used to purchase property and equipment. Cash used for operating activities resulted from the funding of net operating losses and other working capital needs.

At September 30, 2000, the Company had working capital of \$13.1 million, and its cash, cash equivalents and short-term investments totaled \$13.2 million. The Company's working capital decreased by \$3.9 million since December 31, 1999. The decrease was primarily the result of the \$4.3 million decrease in cash, cash equivalents and short-term investments and a \$220,000 increase in accounts receivable.

In January 1998, DATATRAK purchased the EDC software now known as DATATRAK EDC™ from Padcom for \$610,000. The Company is responsible for funding the future development and testing of this software. The Company will also continue to invest in the development of the DATATRAK® process. The Company's sources of cash are cash generated by operations and the maturities of short-term investments. The DATATRAK EDC Business has had a negative cash flow of approximately \$15.1 million since it began operations in 1997. The Company's operations and the EDC market are still in a developmental stage. While the Company has experienced revenue growth in the DATATRAK EDC Business, it anticipates a negative cash flow from operations during 2000, as the Company continues to build its operational and business development infrastructure. The Company anticipates software development and other capital expenditures of \$1.5 million to \$2.0 million over the next fifteen 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.

Year 2000 Disclosure

The Company has completed its Year 2000 remediation efforts and, since January 1, 2000, has not experienced any significant problems internally or with suppliers and customers in connection with this event. Nevertheless, the Company is aware of some remaining future dates that could potentially cause computer system problems, and is continuing to monitor its mission critical computer applications to ensure that any problems are addressed promptly. Because the Company has not, to date, experienced any significant problems in the Year 2000, it does not anticipate any major impact on its operations.

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 DATATRAK EDC Business's revenue for the nine months ended

September 30, 2000 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 Commission 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 EDC 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 DATATRAK business and 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 long-and 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 September 30, 2000.

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: 11/13/00

/s/ Jeffrey A. Green

Jeffrey A. Green,
President and Chief Executive Officer and a Director
(Principal Executive Officer)

Date: 11/13/00

/s/ Terry C. Black

Terry C. Black,
Vice President of Finance, Chief Financial Officer,
Treasurer and Assistant Secretary
(Principal Financial Officer)

Exhibit Index

| Exhibit No. | Description | Page |
|-------------|---|------|
| 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 July 1, 1994* | (A) |
| 10.9 | Employment Agreement between the Company and Terry C. Black, dated July 20, 1994* | (A) |
| 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 January 13, 1998* | (B) |
| 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 | |
| 27.1 | Financial Data Schedule | |

* 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. 000-14699). | |
| (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. 000-14699). | |
| (F) | Incorporated herein by reference to the appropriate exhibit to the Company’s Schedule 14A dated March 17, 1999 (Commission File No. 000-14699). | |
| (G) | Incorporated herein by reference to the appropriate exhibit to the Company’s Schedule 14A dated May 3, 2000 (Commission File No. 000-14699). | |