

DATATRAK INTERNATIONAL INC

Form 10-Q

November 12, 2004

Table of Contents

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, 2004

Commission file number 000-20699

DATATRAK International, Inc.

(Exact name of registrant as specified in its charter)

Ohio

34-1685364

(State or other jurisdiction of
incorporation or organization)

(I.R.S. Employer
Identification No.)

6150 Parkland Boulevard
Mayfield Heights, Ohio

44124

(Address of principal executive
offices)

(Zip Code)

(440) 443-0082

(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 by check mark whether the registrant is an accelerated filer (as defined in Exchange Act Rule 12b-2).
☐ 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, 2004 was 6,101,747.

Table of Contents

TABLE OF CONTENTS

Part I Financial Information

<u>Item 1. Financial Statements</u>	2
<u>Item 2. Managements Discussion and Analysis of Results of Operations and Financial Condition</u>	8
<u>Item 3. Quantitative and Qualitative Disclosures About Market Risk</u>	13
<u>Item 4. Controls and Procedures</u>	13

Part II Other Information

<u>Item 1. Legal Proceedings</u>	14
<u>Item 2. Changes in Securities and Use of Proceeds</u>	14
<u>Item 3. Defaults Upon Senior Securities</u>	14
<u>Item 4. Submission of Matters to a Vote of Security Holders</u>	14
<u>Item 5. Other Information</u>	14
<u>Item 6. Exhibits</u>	14
<u>EX-31.1 CERTIFICATION</u>	
<u>EX-31.2 CERTIFICATION</u>	
<u>EX-32.1 CERTIFICATION</u>	
<u>EX-32.2 CERTIFICATION</u>	

Table of Contents**Part I. Financial Information****Item 1 Financial Statements****DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
CONDENSED CONSOLIDATED BALANCE SHEETS**

	September 30, 2004	December 31, 2003
	(Unaudited)	(Note A)
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,236,587	\$ 1,727,335
Short-term investments	1,988,512	2,533,849
Restricted cash		23,979
Accounts receivable, less allowances	1,456,562	788,342
Prepaid expenses and other current assets	337,720	170,552
Total current assets	6,019,381	5,244,057
Property and equipment, at cost, net of accumulated depreciation and amortization	1,121,396	1,018,739
Other assets		
Restricted cash	72,853	74,189
Deposit	39,549	39,549
	112,402	113,738
Total assets	\$ 7,253,179	\$ 6,376,534
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 349,614	\$ 170,740
Capital lease obligation		23,979
Accrued expenses	809,607	683,846
Deferred revenue	791,400	897,138
Total current liabilities	1,950,621	1,775,703
Shareholders' equity:		
Serial preferred shares, without par value, 1,000,000 shares authorized, none issued		
Common share warrants	68,049	135,424

Common shares, without par value, authorized 25,000,000 shares; issued 9,401,532 shares as of September 30, 2004 and 9,306,053 shares as of December 31, 2003; outstanding 6,101,532 shares as of September 30, 2004 and 6,006,053 shares as of December 31, 2003	56,878,445	56,458,996
Treasury shares, 3,300,000 shares at cost	(20,188,308)	(20,188,308)
Accumulated deficit	(31,388,945)	(31,780,670)
Foreign currency translation	(66,683)	(24,611)
Total shareholders' equity	5,302,558	4,600,831
Total liabilities and shareholders' equity	\$ 7,253,179	\$ 6,376,534

Note A: The balance sheet at December 31, 2003 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.

Table of Contents

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Revenue	\$2,974,536	\$1,895,330	\$7,892,329	\$5,086,555
Direct costs	<u>682,873</u>	<u>411,332</u>	<u>1,820,390</u>	<u>1,110,557</u>
Gross profit	2,291,663	1,483,998	6,071,939	3,975,998
Selling, general and administrative expenses	1,764,272	1,336,139	5,214,310	4,024,478
Depreciation and amortization	<u>140,854</u>	<u>220,826</u>	<u>474,148</u>	<u>713,922</u>
Income (loss) from operations	386,537	(72,967)	383,481	(762,402)
Other income (expense):				
Interest income	11,099	6,121	26,447	16,224
Interest expense		(1,390)	(203)	(5,900)
Other income, net	<u>231</u>	<u>231</u>	<u>747</u>	<u>747</u>
Income (loss) before income taxes	397,636	(68,005)	409,725	(751,331)
Income tax expense	<u>18,000</u>	<u>18,000</u>	<u>18,000</u>	<u>18,000</u>
Net income (loss)	<u>\$ 397,636</u>	<u>\$ (68,005)</u>	<u>\$ 391,725</u>	<u>\$ (751,331)</u>
Net income (loss) per share:				
Basic:				
Net income (loss) per share	<u>\$ 0.07</u>	<u>\$ (0.01)</u>	<u>\$ 0.06</u>	<u>\$ (0.14)</u>
Weighted average shares outstanding	<u>6,095,744</u>	<u>5,705,929</u>	<u>6,072,760</u>	<u>5,424,785</u>
Diluted:				
Net income (loss) per share	<u>\$ 0.06</u>	<u>\$ (0.01)</u>	<u>\$ 0.06</u>	<u>\$ (0.14)</u>
Weighted average shares outstanding	6,815,027	5,705,929	6,787,286	5,424,785

See notes to condensed consolidated financial statements.

Table of Contents

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

	Nine Months Ended September 30,	
	2004	2003
Operating Activities		
Net income (loss)	\$ 391,725	\$ (751,331)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	474,148	713,922
Stock compensation	26,056	60,331
Other	21,073	5,639
Changes in operating assets and liabilities:		
Accounts receivable	(707,820)	83,030
Prepaid expenses and other current assets	(167,971)	(117,853)
Accounts payable and accrued expenses	304,635	(220,129)
Deferred revenue	(105,738)	205,037
Net cash provided by (used in) operating activities	236,108	(21,354)
Investing activities		
Decrease in restricted cash	23,979	102,916
Purchases of property and equipment	(579,456)	(44,298)
Maturities of short-term investments	6,786,021	2,635,084
Purchases of short-term investments	(6,222,157)	(4,568,657)
Net cash provided by (used in) investing activities	8,387	(1,874,955)
Financing activities		
Proceeds from issuance of common shares and stock option exercises	326,018	2,248,151
Payments under capital lease obligation	(23,979)	(102,916)
Repayment (issuance) of notes receivable, net	803	(4,065)
Net cash provided by financing activities	302,842	2,141,170
Effect of exchange rate on cash	(38,085)	(17,131)
Increase in cash and cash equivalents	509,252	227,730
Cash and cash equivalents at beginning of period	1,727,335	1,620,707

Cash and cash equivalents at end of period	\$ 2,236,587	\$ 1,848,437
---	---------------------	---------------------

See notes to condensed consolidated financial statements.

Table of Contents

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2004
(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 and nine month periods ended September 30, 2004 are not necessarily indicative of the results that may be expected for the year ending December 31, 2004. 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, 2003 (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 Income (Loss) per Share

The following table sets forth the computation of basic and diluted net income (loss) per share.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income (loss) used in the calculation of basic and diluted loss per share	\$ 397,636	\$ (68,005)	\$ 391,725	\$ (751,331)
Denominator for basic net income (loss) per share — weighted average common shares outstanding	6,095,744	5,705,929	6,072,760	5,424,785
Effect of dilutive common share options and warrants	719,283		727,421	
Denominator for diluted net income (loss) per share	6,815,027	5,705,929	6,787,286	5,424,785

Edgar Filing: DATATRAK INTERNATIONAL INC - Form 10-Q

Basic net income (loss) per share	\$ 0.07	\$ (0.01)	\$ 0.06	\$ (0.14)
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Diluted net income (loss) per share	\$ 0.06	\$ (0.01)	\$ 0.06	\$ (0.14)
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Weighted average common share options and warrants excluded from the computation of diluted net income (loss) per share because they would have an antidilutive effect on net income (loss) per share	46,750	1,238,580	39,773	1,232,459
	<u> </u>	<u> </u>	<u> </u>	<u> </u>

Table of Contents

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2004
(Unaudited)

3. Comprehensive Income (Loss)

The following table sets forth comprehensive income (loss).

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income (loss)	\$397,636	\$(68,005)	\$391,725	\$(751,331)
Foreign currency translation	(240)	8,589	(42,072)	8,110
Comprehensive income (loss)	<u>\$397,396</u>	<u>\$(59,416)</u>	<u>\$349,653</u>	<u>\$(743,221)</u>

4. Shareholders' Equity

During January 2004, the holders of 12,500 common share warrants, with an exercise price of \$4.80 per share, surrendered the warrants along with the exercise price in exchange for 12,500 common shares. In addition, during the nine months ended September 30, 2004, the holders of 82,979 common share options, at a weighted average exercise price of \$3.21 per share, exercised the options and purchased 82,979 common shares.

On June 2, 2004, the Company's shareholders voted to approve and adopt an amendment and restatement to the Company's Amended and Restated Outside Director Stock Option Plan (f/k/a Amended and Restated 1999 Outside Director Stock Option Plan) (the Director Plan). As part of this amendment and restatement, the number of shares reserved for stock option grants to outside directors of the Company, under the Director Plan, increased from 400,000 to 550,000.

5. Income Taxes

During the nine months ended September 30, 2004, the Company had U.S. federal alternative minimum tax of \$18,000 due to income earned by its U.S. based operations. Due to its U.S. and non-U.S. tax loss carryforwards, the Company had no other income tax expense during the nine months ended September 30, 2004.

6. Stock Based Compensation

The Company has elected to follow Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB No. 25) and related interpretations in accounting for its employee and director stock options. Under APB No. 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. The alternative fair value accounting provided for under Financial Accounting

Standards Board (FASB) Statement of Financial Accounting Standards (SFAS) No. 123, Accounting for Stock-Based Compensation requires use of option valuation models that were not developed for use in valuing employee stock options. SFAS No. 148, Accounting for Stock-Based Compensation Transition and Disclosure, requires disclosure of compensation expense under both APB No. 25 and SFAS No. 123. SFAS No. 123 requires that stock compensation be determined as if the Company has accounted for its stock options granted subsequent to December 31, 1994 under the fair value method of SFAS 123.

Table of Contents

DATATRAK INTERNATIONAL, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
September 30, 2004
(Unaudited)

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 No. 123.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2004	2003	2004	2003
Net income (loss) recorded	\$ 397,636	\$ (68,005)	\$ 391,725	\$ (751,331)
Plus: stock compensation expense recognized	14,142	9,132	26,056	60,331
Less: stock compensation expense that would have been recognized under SFAS No. 123	<u>213,113</u>	<u>365,481</u>	<u>524,307</u>	<u>532,872</u>
Pro forma net income (loss)	<u>\$ 198,665</u>	<u>\$ (424,354)</u>	<u>\$ (106,526)</u>	<u>\$ (1,223,872)</u>
Pro forma basic income (loss) per share	<u>\$ 0.03</u>	<u>\$ (0.08)</u>	<u>\$ (0.02)</u>	<u>\$ (0.23)</u>
Pro forma diluted income (loss) per share	<u>\$ 0.03</u>	<u>\$ (0.08)</u>	<u>\$ (0.02)</u>	<u>\$ (0.23)</u>

7. Reclassification

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

Table of Contents

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, 2004 is derived from, and should be read in conjunction with, 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 a provider of software and other related services, commonly referred to as an application service provider, or ASP. DATATRAK's customers use the software known as DATATRAK EDC® to collect and transmit clinical trial data, commonly referred to as electronic data capture, or EDC. The Company's services assist companies in the clinical pharmaceutical, biotechnology, contract research organization and medical device research industries, in accelerating the completion of clinical trials. Approximately 59% of the Company's assets, or approximately \$4,225,000, is held in cash, cash equivalents and short-term investments. During 2004, and for the first time since commencing EDC operations in 1997, the Company has recorded net income from operations. The Company is continuing to enhance and commercialize its business and the DATATRAK EDC® software, and anticipates that its operating results may fluctuate significantly from period to period. There can be no assurance of the Company's long-term future prospects.

The Company's standard contracts provide a fixed unit price for each component or service to be delivered, and revenue is recognized as these components or services are 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. Generally, these contracts range in duration from one to three years. The ultimate contract value is dependent upon the length of the customer's use of DATATRAK EDC® and the services DATATRAK provides. As services are performed over the life of the contract, revenue is recognized per the specific terms of each contract. Costs associated with contract revenue are recognized as incurred. Pass-through costs that are paid directly by DATATRAK's customers, and for which the Company does not bear the risk of economic loss, are excluded from revenue. The termination of a standard contract will not result in a material adjustment to the revenue or costs previously recognized.

In some instances, DATATRAK offers volume discounts to customers over multiple contracts. DATATRAK estimates the volume discounts to be earned over the life of the contracts to which the discount applies. As contracts progress, revenue is recorded using rates that reflect the anticipated volume discount to be achieved by the customer. The termination of a contract subject to a volume discount could result in a material adjustment to revenue previously recognized, in order to reflect the true economic value of the contract at the time of cancellation. For the nine months ended September 30, 2004, DATATRAK has deferred \$49,000 of revenue as a result of its contracts subject to volume discounts.

Since its purchase of the DATATRAK EDC® software in January 1998, DATATRAK has recorded revenue related to approximately one hundred contracts. Backlog consists of anticipated revenue from authorization letters to commence services and signed contracts yet to be completed. Potential contracts or authorization letters that have passed the verbal stage, but have not yet been signed, are excluded from backlog. At September 30, 2004, DATATRAK's backlog was \$14,298,000. DATATRAK's contracts can be cancelled or delayed at anytime and, therefore, the Company's backlog, at any point in time, is not an accurate predictor of future levels of revenue.

Critical Accounting Policies

In response to the SEC's Release No. 33-8040, "Cautionary Advice Regarding Disclosure About Critical Accounting Policies," the Company has identified the most critical accounting principles upon

Table of Contents

which its financial status depends. Critical principles were determined by considering accounting policies that involve the most complex or subjective decisions or assessments. The most critical accounting policies were identified to be those related to revenue recognition, software development costs and stock based compensation.

A summary of these critical accounting policies can be found in the Company's Annual Report on Form 10-K, filed on March 19, 2004, under the heading "Critical Accounting Policies" in Management's Discussion and Analysis of Financial Condition and Results of Operations.

Results of Operations

Three months ended September 30, 2004 compared with three months ended September 30, 2003

Revenue for the three months ended September 30, 2004 increased 56.9% to \$2,975,000, as compared to \$1,895,000 for the three months ended September 30, 2003. During the third quarter of 2004, DATATRAK recorded revenue related to 59 contracts compared to 42 contracts during 2003. Additionally, for the three months ended September 30, 2004, \$2,315,000 of revenue was the result of contracts that were in backlog at December 31, 2003 and \$660,000 was the result of new business. For the third quarter of 2003, \$1,133,000 of revenue was generated from contracts that were in backlog at December 31, 2002 and \$762,000 of revenue was the result of new business.

Direct costs of revenue, mainly personnel costs, were \$683,000 and \$411,000 during the three months ended September 30, 2004 and 2003, respectively. Additional staff and other payroll cost increases accounted for \$221,000 of the \$272,000 increase. Other direct costs, which include third-party software license fees, travel and other costs billed directly to DATATRAK's customers, increased by \$51,000 during the three months ended September 30, 2004. The increase in staff was necessitated by the growth in revenue and the increase in the number of contracts DATATRAK has been managing over the past year. DATATRAK's gross margin decreased to 77.0% for the three months ended September 30, 2004 compared to 78.3% for the three months ended September 30, 2003.

Selling, general and administrative (SG&A) expenses include all administrative personnel costs, business and software development costs, and all other expenses not directly chargeable to a specific contract. SG&A expenses increased by 32.0 % to \$1,764,000 from \$1,336,000 for the three months ended September 30, 2004 and 2003, respectively. Additional staff, other payroll cost increases and the Company's new sales incentive plan accounted for \$183,000 of the \$428,000 increase. Expenses related to equipment maintenance and software licensing increased \$68,000 compared to the prior year. These expenses are necessary to ensure that DATATRAK's information technology environment is properly maintained. Cost increases in other areas, primarily due to the increased marketing of DATATRAK EDC® and development of the Company's corporate infrastructure, resulted in additional expenses of \$177,000 during the three months ended September 30, 2004.

Depreciation and amortization expense decreased to \$141,000 during the three months ended September 30, 2004 from \$221,000 during the three months ended September 30, 2003. The decrease was the result of aging assets not being replaced as indicated by the low level of capital expenditures (\$184,000) during 2003. During the first nine months of 2004, DATATRAK spent \$579,000 for new equipment. The Company expects increased capital expenditure activity throughout the remainder of 2004.

Nine months ended September 30, 2004 compared with nine months ended September 30, 2003

Revenue for the nine months ended September 30, 2004 increased 55.1% to \$7,892,000, as compared to \$5,087,000 for the nine months ended September 30, 2003. Included in revenue for the nine months ended September 30, 2003, was a one-time consulting fee of \$150,000 that was outside of a traditional EDC contract. During the nine months ended September 30, 2004, DATATRAK recorded revenue related to 65 contracts compared to 51

contracts during 2003. For the nine months ended September 30, 2004, \$6,797,000 of revenue was the result of contracts that were in backlog at December

Table of Contents

31, 2003 and \$1,096,000 was the result of new business. For the nine months ended September 30, 2003, \$3,626,000 of revenue was generated from contracts that were in backlog at December 31, 2002 and \$1,460,000 of revenue was the result of new business.

Direct costs of revenue, mainly personnel costs, were \$1,820,000 and \$1,111,000 during the nine months ended September 30, 2004 and 2003, respectively. Additional staff and other payroll cost increases accounted for \$573,000 of the \$709,000 increase in 2004. Other direct costs, which include third-party software license fees, travel and other costs billed directly to DATATRAK's customers, increased by \$136,000 during the nine months ended September 30, 2004. The increase in staff was necessitated by the growth in revenue and the increase in the number of contracts DATATRAK has been managing over the past year. DATATRAK's gross margin decreased to 76.9% for the nine months ended September 30, 2004 compared to 78.2% for the nine months ended September 30, 2003. The \$150,000 one-time revenue item caused a 0.7% increase in gross margin during the first nine months of 2003.

SG&A expenses increased by 29.6% to \$5,214,000 from \$4,024,000 for the nine months ended September 30, 2004 and 2003, respectively. Additional staff, other payroll cost increases and the Company's new sales incentive plan accounted for \$470,000 of the \$1,190,000 increase. Expenses related to equipment maintenance and software licensing increased \$133,000 compared to the prior year. The increase in these expenses is related to the growth of DATATRAK's information technology infrastructure, and are necessary to ensure that this environment is properly maintained. Cost increases in other areas, primarily due to the increased marketing of DATATRAK EDC®, non-capitalized software development costs and development of the Company's corporate infrastructure, resulted in additional expenses of \$587,000 during the nine months ended September 30, 2004.

Depreciation and amortization expense decreased to \$474,000 during the nine months ended September 30, 2004 from \$714,000 during the nine months ended September 30, 2003. The decrease was the result of aging assets not being replaced as indicated by the low level of capital expenditures during 2003.

Other income increased to \$26,000 during the nine months ended September 30, 2004 from \$11,000 during the nine months ended September 30, 2003. Other income includes interest income which increased \$10,000 for the nine months ended September 30, 2004 compared to September 30, 2003, as a result of the Company's increase in cash and cash equivalents due to its August 2003 private placement of common shares. Interest expense decreased by \$6,000 due to the payment in full of the Company's capital lease obligation during 2004.

During the nine months ended September 30, 2004, the Company had U.S. federal alternative minimum tax of \$18,000 due to income earned by its U.S. based operations. Due to its U.S. and non-U.S. tax loss carryforwards, the Company had no other income tax expense during the nine months ended September 30, 2004.

Outlook

Primarily due to its growth in revenue, DATATRAK reported net income for the three and nine months ended September 30, 2004. Backlog at September 30, 2004 of \$14,298,000 remained comparable to backlog reported at December 31, 2003 of \$14,600,000 because new contract signings and modifications to existing contracts have kept pace with revenue recognized on contracts in backlog. At September 30, 2004 the Company had 56 contracts in backlog, compared to 45 contracts in backlog at December 31, 2003.

Assuming that there are no contract delays or cancellations to current projects, the Company's management believes that it will achieve the lower end of its earlier reported guidance of \$11,000,000 to \$13,000,000 of revenue for the year ended December 31, 2004. The Company expects to convert approximately \$2,800,000 of its September 30, 2004 backlog into revenue during the final three months of 2004. Based on its anticipated levels of revenue and expenses, DATATRAK's management does not believe that it will achieve its earlier reported guidance of fully diluted earnings

per share of \$0.13, for the

Table of Contents

year ended December 31, 2004. Shareholders should anticipate fully diluted earnings per share of approximately \$0.08 for the year ended December 31, 2004, based on current shares outstanding.

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. The Company's investing activities primarily reflect capital expenditures and sales and purchases of short-term investments. In August 2003, the Company raised approximately \$2,239,000 in cash with the completion of a private placement of its common shares.

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 monthly as work on the contract progresses. 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. DATATRAK's accounts receivable fluctuates due to the timing and size of cash receipts. Contracting and collection practices are designed to maintain an average collection period for accounts receivable of one to three months. Any increase in the Company's normal collection period for accounts receivable could negatively impact its cash flow from operations and working capital. At September 30, 2004, the average collection period for accounts receivable was 42 days compared to 43 days at December 31, 2003. Accounts receivable (net of allowance for doubtful accounts) was \$1,457,000 at September 30, 2004 and \$788,000 at December 31, 2003. DATATRAK's increased revenue has caused the accounts receivable balance to increase during 2004, however the accounts receivable collection period has remained consistent with prior periods. Deferred revenue was \$791,000 at September 30, 2004 compared to \$897,000 at December 31, 2003.

Cash and cash equivalents increased \$528,000 during the three months ended September 30, 2004. This was the result of \$862,000 provided by operating activities, \$380,000 used in investing activities and \$50,000 provided by investing activities. Foreign currency fluctuations caused a \$4,000 decrease in cash and cash equivalents. Cash provided by operating activities was the result of the Company's net income of \$398,000, plus non cash operating items of \$160,000. Changes in current assets and liabilities caused cash from operating activities to increase by \$304,000. Investing activities included \$397,000 used to purchase property and equipment, offset by net maturities of investments totaling \$17,000. Financing activities included proceeds from the issuance of common shares totaling \$50,000 as the result of exercises of common share options.

Cash and cash equivalents increased \$509,000 during the nine months ended September 30, 2004. This was the result of \$236,000 provided by operating activities and \$311,000 provided by investing and financing activities. Foreign currency fluctuations caused a \$38,000 decrease in cash and cash equivalents. Cash provided by operating activities was the result of the Company's net income of \$392,000, plus non cash operating items of \$521,000. This \$913,000 increase was offset by the \$708,000 increase in accounts receivable caused by the Company's growth in revenue during 2004. Changes in other current assets and liabilities caused cash from operating activities to increase by \$31,000. Investing activities included \$579,000 used to purchase property and equipment, offset by net maturities of investments and a decrease in restricted cash totaling \$588,000. Financing activities included proceeds from the issuance of common shares totaling \$326,000 as the result of exercises of common share options and warrants, which was partially offset by capital lease payments totaling \$24,000.

At September 30, 2004, the Company had working capital of \$4,069,000 and its cash, cash equivalents and short-term investments totaled \$4,225,000. The Company's working capital increased by \$600,000 since December 31, 2003. The increase was primarily the result of a \$774,000 increase in net accounts receivable (accounts receivable less deferred revenue). Cash, cash equivalents and short-term investments decreased by \$36,000 during the nine months ended September 30, 2004. Changes in other current assets and liabilities caused working capital to decrease by

\$138,000.

Table of Contents

The Company is responsible for funding the future enhancement 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 revenue growth, and anticipates recording net income and positive cash flow from operations for the year ended December 31, 2004, as it continues to build its customer base, increase its backlog and convert existing backlog into revenue. During the nine months ended September 30, 2004, the Company expended \$579,000 for capital expenditures, and had expenditures totaling \$386,000 for equipment maintenance and related items. The Company anticipates additional capital and related expenditures of approximately \$584,000 through the end of 2004 for continued commercialization, product development and maintenance of DATATRAK EDC® and the anticipated growth of DATATRAK's business and information technology infrastructure. DATATRAK expects to fund these working capital requirements, from existing cash and cash equivalents, cash flow from operations and maturities of short-term investments. The Company believes that its cash and cash equivalents, maturities of short-term investments and anticipated cash flow from operations will be sufficient to meet its working capital and capital expenditure requirements for the foreseeable future. However, DATATRAK may need to raise additional funds to support expansion, respond to competitive pressures, acquire complementary businesses or technology or take advantage of unanticipated opportunities. Additional funds may be raised by selling debt or equity securities, by entering into strategic relationships or through other arrangements. Additional capital may not be available on acceptable terms, if at all. To the extent that additional equity capital is raised, it could have a dilutive effect on existing shareholders.

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.

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, as amended (Exchange Act). In addition, words such as expects, anticipates, intends, plans, believes, estimates, variations, 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 of 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; 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 all inclusive. 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. Any forward-looking statement speaks only as of the date on which such statement is made and the Company does not undertake any obligation to update any statements whether as a result of new information, future events or otherwise.

Table of Contents

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 Euros. A summary of the Company's market risk exposures is presented below.

Interest Rate Risk

DATATRAK 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. A 1.0% change in interest rates during the nine months ended September 30, 2004, would have resulted in a \$32,000 change in DATATRAK's interest income during the period.

Foreign Currency Risk

DATATRAK's foreign results of operations are subject to the impact of foreign currency fluctuations through both foreign currency transaction and foreign currency translation adjustments. The Company manages its risk to foreign currency transaction adjustments by maintaining foreign currency bank accounts in currencies in which we regularly transact business. DATATRAK does not currently hedge against the risk of exchange rate fluctuations.

DATATRAK's financial position and results of operations are impacted by translation adjustments caused by the conversion of foreign currency accounts and operating results into U.S. dollars for financial reporting purposes. A 1.0% fluctuation in the exchange rate between the U.S. dollar and the Euro at September 30, 2004, would have resulted in a \$27,000 change in the foreign currency translation amount recorded on the Company's balance sheet, due to foreign currency translations. A 1.0% fluctuation in the average exchange rate between the U.S. dollar and the Euro for the nine months ended September 30, 2004 would have resulted in a \$26,000 change in the Company's net income for the nine months ended September 30, 2004 due to foreign currency translations. During the nine months ended September 30, 2004, the average exchange rate between the Euro and the U.S. dollar increased by approximately 10% compared to the nine months ended September 30, 2003. The conversion of the Company's foreign operations into U.S. dollars upon consolidation resulted in net income that was approximately \$240,000 lower than would have been recorded had the exchange rate between the Euro and the U.S. dollar remained consistent with 2003 rates.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The Company carried out an evaluation, under the supervision and with the participation of the Company's management, including the chief executive officer and chief financial officer, of the design and operation of the Company's disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-14(e)) as of the end of the period covered by this report. Based upon that evaluation the Company's management, including the chief executive officer and chief financial officer, have concluded that, as of September 30, 2004, the Company's disclosure controls and procedures were effective to ensure that material information relating to the Company and its consolidated subsidiaries would be made known to them by others within those entities, so that information required to be disclosed by the Company in the reports it files and submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Table of Contents

Changes in Internal Controls

There were no changes in the Company's internal controls over financial reporting that occurred during the fiscal quarter covered by this report that have materially affected, or are reasonably likely to materially affect, the Company's internal controls over financial reporting.

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

31.1 Rule 13a-14(a)/15d-14(a) Certification of Chief Executive Officer

31.2 Rule 13a-14(a)/15d-14(a) Certification of Chief Financial Officer

32.1 Section 1350 Certification of Chief Executive Officer

32.2 Section 1350 Certification of Chief Financial Officer

Table of Contents

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: 11/12/04

/s/ Jeffrey A. Green

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

Date: 11/12/04

/s/ Terry C. Black

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