

DATATRAK INTERNATIONAL INC

Form S-3

January 12, 2005

**Table of Contents**

**AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON JANUARY 12, 2005**

**REGISTRATION NO. 333-\_\_\_\_\_**

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**SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM S-3**

**REGISTRATION STATEMENT  
Under The Securities Act Of 1933**

**DATATRAK International, Inc.**

(Exact name of Registrant as Specified in its Charter)

**Ohio**

(State or Other Jurisdiction of Incorporation or Organization)

**34-1685364**

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

**6150 Parkland Boulevard  
Mayfield Heights, Ohio 44124  
(440) 443-0082**

(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

**Jeffrey A. Green  
President and Chief Executive Officer  
DATATRAK International, Inc.  
6150 Parkland Boulevard  
Mayfield Heights, Ohio 44124  
(440) 443-0082**

(Name, Address, Including Zip Code, and Telephone Number, Including Area Code, of Agent For Service)

**Copy To:  
Thomas F. McKee, Esq.  
Calfee, Halter & Griswold LLP  
1400 McDonald Investment Center  
800 Superior Avenue  
Cleveland, Ohio 44114-2688  
(216) 622-8200**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box.

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

**CALCULATION OF REGISTRATION FEE**

| <b>Title Of Shares</b>           | <b>Amount To Be Registered</b> | <b>Proposed Maximum Aggregate Price Per Unit(2)</b> | <b>Proposed Maximum Aggregate Offering Price(2)</b> | <b>Amount Of Registration Fee</b> |
|----------------------------------|--------------------------------|---|---|-----------------------------------|
| <b>To Be Registered(1)</b>       |                                |   |   |                                   |
| Common Shares, without par value | 580,577                        | \$ 10.59  | \$ 6,148,310.40                                     | \$ 723.66                         |

(1) Includes rights to purchase common shares under the registrant's Rights Agreement that, prior to the occurrence of certain events, will not be exercisable or evidenced separately from the common shares. Also includes 94,264 common shares issuable upon the exercise of

**Table of Contents**

outstanding warrants and such indeterminate number of common shares as may be issuable pursuant to the anti-dilution provisions contained therein.

- (2) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(c) under the Securities Act, based on the average of the high and low sale prices reported for the common shares on the Nasdaq SmallCap Market on January 6, 2005.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.**

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**Table of Contents**

The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and we are not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

**PROSPECTUS**

**DATATRAK International, Inc.**

**580,577 Common Shares**

The selling shareholders are offering 580,577 of our common shares. Of these 580,577 common shares, 486,313 were acquired by certain selling shareholders pursuant to the share purchase agreement, dated as of December 23, 2004, among us and certain selling shareholders. In addition, 72,948 common shares may be acquired at \$14.40 per share upon the exercise of warrants issued to certain selling shareholders and 21,316 common shares may be acquired at \$14.40 per share upon the exercise of warrants issued to a placement agent, both as a result of the consummation of the share purchase agreement, dated as of December 23, 2004. We will not receive any of the proceeds from the sale of the common shares by the selling shareholders.

Our common shares trade on the Nasdaq SmallCap Market under the symbol DATA. On January 11, 2005, the closing price of our common shares on the Nasdaq SmallCap Market was \$11.12.

The selling shareholders may sell the common shares from time to time through public or private transactions, on or off the Nasdaq SmallCap Market, at prevailing prices or at privately negotiated prices.

**Investing in our common shares involves risks. See Risk Factors beginning on page 2.**

**NEITHER THE SECURITIES AND EXCHANGE COMMISSION NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.**

The date of this prospectus is January \_\_, 2005.

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**TABLE OF CONTENTS**

|  | <b>Page</b> |
|--|-------------|
| <u>SUMMARY</u>                             | 1           |
| <u>RISK FACTORS</u>                        | 2           |
| <u>FORWARD-LOOKING STATEMENTS</u>          | 4           |
| <u>THE COMPANY</u>                         | 5           |
| <u>USE OF PROCEEDS</u>                     | 6           |
| <u>THE SELLING SHAREHOLDERS</u>            | 6           |
| <u>PLAN OF DISTRIBUTION</u>                | 7           |
| <u>LEGAL MATTERS</u>                       | 10          |
| <u>EXPERTS</u>                             | 10          |
| <u>WHERE YOU CAN FIND MORE INFORMATION</u> | 10          |

INCORPORATION BY REFERENCE

10

EX-5.1 Opinion of Calfee Halter & Griswold

EX-23.1 Consent of Independent Accountants - Ernst & Young

i

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**Table of Contents**

**SUMMARY**

*This summary highlights information contained in this prospectus. This summary is not complete and does not contain all the information that you should consider before investing in our common shares. You should read the entire prospectus carefully.*

**DATATRAK International, Inc.**

We are a provider of software and other related services, commonly referred to as an application service provider, or ASP. Our customers use our software to collect and transmit clinical trial data electronically, commonly referred to as electronic data capture, or EDC. Our customers are companies in the clinical pharmaceutical, biotechnology, contract research organization and medical device research industries. Our services assist these companies to accelerate completion of clinical trials by streamlining the collection of data relating to those clinical trials, improving the quality of the data collected and thus reducing the time required to review the results of each clinical trial.

Our principal executive offices are located at 6150 Parkland Boulevard, Mayfield Heights, Ohio 44124. Our telephone number is (440) 443-0082.

**The Offering**

**Securities Offered**

DATATRAK common shares that were acquired by certain selling shareholders pursuant to the share purchase agreement, dated as of December 23, 2004, as well as common shares that may be acquired upon the exercise of warrants issued to certain selling shareholders and a placement agent, both as a result of the consummation of the share purchase agreement, dated as of December 23, 2004.

**Number of Securities Offered**

The selling shareholders are offering 580,577 of our common shares. Of these 580,577 common shares, 486,313 were acquired by certain selling shareholders pursuant to the share purchase agreement, dated as of December 23, 2004, among us and certain selling shareholders. Additionally, 72,948 common shares may be acquired at \$14.40 per share upon the exercise of warrants issued to certain selling shareholders and 21,316 common shares may be acquired at \$14.40 per share upon the exercise of warrants issued to a placement agent, both as a result of the consummation of the share purchase agreement, dated as of December 23, 2004.

**Nasdaq Ticker Symbol**

DATA

**Use of Proceeds**

All of the common shares offered under this prospectus are being sold by the selling shareholders. We will not receive any of the proceeds from the sale of these common shares.

**Risk Factors**

You should carefully read and consider, in addition to the matters set forth elsewhere in this prospectus and contained in the registration statement we have filed with the Securities and Exchange Commission, the information in

the Risk Factors section beginning on page 2.



**Table of Contents**

**RISK FACTORS**

*You should carefully consider the following risk factors and other information before deciding to invest in our common shares.*

**We have a limited operating history and we have not until recently had profitable operations.**

We began providing EDC services in 1997 and we have a limited operating history upon which you may evaluate our performance. We have recognized operating losses in each year since 1997. Although we were profitable for the nine month period ended September 30, 2004, with net income from operations of approximately \$398,000, any number of factors, including, but not limited to, termination or delays in contracts, inability to grow and convert backlog into revenue or being able to quickly reduce costs if required, could cause us to record losses in future periods. Our cumulative operating loss since 1997 from our EDC operations totaled \$39 million at September 30, 2004.

**If we do not continue to enhance our software, we may not be able to meet the evolving needs of our customers.**

Although our proprietary DATATRAK EDC® software has been used in clinical trials, continued enhancement is necessary to provide additional functions and services to meet the ever-changing needs and expectations of our customers. To date, we have had limited EDC revenue from which to support the costs of this continued software enhancement. Our potential future revenue may not be sufficient to allow us to absorb corporate overhead and other fixed operating costs necessary for the success of the DATATRAK® process.

**Our quarterly results fluctuate significantly.**

We are subject to significant fluctuations in quarterly results caused by many factors, including

our success in obtaining new contracts,

the size and duration of the clinical trials in which we participate, and

the timing of clinical trial sponsor decisions to conduct new clinical trials or cancel or delay ongoing trials. Our expense levels are based in part on our expectations as to future revenue and, to a certain extent, are fixed. We cannot assure you as to our revenues in any given period, and we may be unable to adjust expenses in a timely manner to compensate for any unexpected revenue shortfall. As a result of our relatively small revenue base, any significant shortfall in revenue recognized during a particular period could have an immediate adverse effect on our results of operations and financial condition. Volatility in our quarterly results may adversely affect the market price of our common shares.

**Our business strategies are unproven and we are in an early stage of development.**

Our efforts to establish a standardized EDC process for collection and management of clinical research data represent a significant departure from the traditional clinical research practices of clinical trial sponsors. The long-term viability of our business remains unproven. Our strategy may not gain acceptance among sponsors of clinical research, research sites or investigators. You should consider our prospects in light of the risks, expenses and difficulties frequently encountered by companies in their early stages of development, and particularly companies in new and rapidly evolving markets.



**Table of Contents**

**We may lose revenues if we experience delays in clinical trials or if we lose contracts.**

Although our contracts provide that we are entitled to receive revenue earned through the date of termination, our customers generally are free to delay or terminate a clinical trial or our contract related to the trial at any time. The length of a typical clinical trial contract varies from several months to several years. Clinical trial sponsors may delay or terminate clinical trials for several reasons, including

- unexpected results or adverse patient reactions to a potential product,
- inadequate patient enrollment or investigator recruitment,
- manufacturing problems resulting in shortages of a potential product, or
- decisions by the sponsor to de-emphasize or terminate a particular trial or drug.

We may lose revenues if a clinical trial sponsor decides to delay or terminate a trial in which we participate.

**We may lose revenues if our major customers decrease their research and development expenditures, or if we lose any of our major customers.**

Our primary customers are companies in the pharmaceutical industry. Our business is substantially dependent on the research and development expenditures of companies in this industry. The extent to which we rely on revenue from one or more major customers varies from period to period depending upon, among other things, our ability to generate new business and the timing and size of clinical trials. In light of our small revenue base, we are more dependent on major customers than many of our larger competitors in the EDC industry. During the twelve months ended December 31, 2003, three customers accounted for approximately 53% of our total revenue. Additionally, during the nine months ended September 30, 2004, two customers accounted for approximately 55% of our total revenue. Our operations could be materially and adversely affected by, among other things,

- any economic downturn or consolidations in the pharmaceutical or biotechnology industries,
- any decrease in those industries' research and development expenditures, or
- a change in the regulatory environment in which companies in these industries operate.

**Changes in government regulations relating to the health care industry could have a material adverse effect on the demand for our services.**

Demand for our services is largely a function of the regulatory requirements associated with the approval of a new drug application by the FDA. These requirements are stringent and are more burdensome than those imposed by many other developed countries. In recent years, efforts have been made to streamline the drug approval process and coordinate U.S. standards with those of other developed countries. Changes in the level of regulation, including a relaxation in regulatory requirements or the introduction of simplified drug approval procedures, could reduce the demand for our services. Several competing proposals to reform the system of health care delivery in the U.S. have been considered by Congress from time to time. To date, none of these proposals has been adopted.

The FDA's guidelines and rules related to the use of computerized systems in clinical trials are still in the early stages of development. The DATATRAK® process may not continue to comply with these guidelines and rules as they develop, and corresponding changes to our product may be required. Any release of FDA guidance that is significantly inconsistent with the design of DATATRAK EDC® may cause us to incur substantial costs to remain in compliance with FDA guidance and regulations.

**We may not be able to capture or establish the market presence necessary to compete in the EDC market.**

The EDC market, which is still developing and must compete with the traditional paper method of

## **Table of Contents**

collecting clinical trial data, is highly fragmented. The major competitors in the EDC market include

EDC software vendors,

clinical trial data service companies that use paper for data collection, and

in-house development efforts within large pharmaceutical companies.

Our current and potential future competitors may have substantially greater resources, greater name recognition and more extensive customer bases that could be leveraged, thereby gaining market share or product acceptance to our detriment. We may not be able to capture or establish the market presence necessary to effectively compete in this emerging sector of the clinical research industry.

### **We may be subject to liability for potential breaches of contract or losses relating to the unauthorized release of clinical trial data.**

Our services are supported by telecommunications equipment, software, operating protocols and proprietary applications for high-speed transmission of large quantities of data among multiple locations. In addition, clinical pharmaceutical and medical device research requires the review and handling of large amounts of patient data. Potential liability may arise from a breach of contract or a loss or unauthorized release of clinical trial data. If we were forced to undertake the defense of, or were found financially responsible for, claims based upon these types of losses or unauthorized releases, our financial resources could be diminished. We maintain a \$5 million errors and omissions professional liability policy to cover claims that may be brought against us. This coverage may not be adequate, and insurance may not continue to be available to us in the future.

### **The price of our common shares could be adversely affected by the dilution caused by the sale of the common shares issued to the selling shareholders.**

In December 2004, we sold 486,313 of our common shares to certain selling shareholders at a price of \$9.50 per share, issued warrants to purchase an additional 72,948 common shares at \$14.40 to those selling shareholders and issued warrants to purchase 21,316 common shares at \$14.40 to a placement agent, all as a result of the consummation of the share purchase agreement, dated as of December 23, 2004. These 580,577 common shares represent, assuming issuance of the 94,264 common shares underlying the warrants, 8.7% of our outstanding common shares. Sales of a substantial number of these common shares in the public market could depress the market price of our common shares. The perceived risk resulting from the sale of these common shares could cause some of our shareholders to sell their common shares, thus causing the price of our common shares to further decline. In addition, the downward pressure on the price of our common shares could cause some of our shareholders to engage in short sales of our common shares, which may cause the price of our common shares to decline even further.

## **FORWARD-LOOKING STATEMENTS**

This prospectus, and the information incorporated by reference in this prospectus, contains forward-looking statements, within the meaning of federal securities laws, about our financial condition, results of operations and business. You can find many of these statements by looking for words like expects, anticipates, intends, plans, believes and estimates or similar expressions used in this prospectus. These forward-looking statements are subject to numerous assumptions and risks and uncertainties that may cause our actual results or performance to be materially different from any future results or performance expressed or implied by the forward-looking statements. These risks and uncertainties include those identified under the heading Risk Factors in this prospectus. These factors include, but are not limited to,

our ability 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,

**Table of Contents**

our 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 clinical trials,

government regulations effecting us,

the early stage of our application service provider, or ASP, operations, and

general economic conditions, such as the rate of employment, inflation, interest rates and the condition of the capital markets.

Because these forward-looking statements are subject to risks and uncertainties, we caution you not to place undue reliance on these statements, which speak only as to the date of this prospectus. We do not undertake any responsibility to review or confirm analysts' expectations or estimates or to release publicly any revisions to these forward-looking statements to take into account events or circumstances that occur after the date of this prospectus. In addition, we do not undertake any responsibility to update you on the occurrence of unanticipated events which may cause actual results to differ from those expressed or implied by these forward-looking statements.

**THE COMPANY**

DATATRAK International, Inc. is an ASP that provides EDC and other services to companies in the clinical pharmaceutical, biotechnology, contract research organization and medical device research industries. Our services assist these companies in accelerating completion of clinical trials by streamlining the collection of data relating to clinical trials, improving the quality of the data collected, and thus reducing the time required to review the results of each clinical trial.

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

We began EDC operations in 1997. During that year, we participated in a joint venture with IBM Global Services to develop and market a data collection and management system for use in clinical trials. The joint venture was subsequently terminated, and in January 1998, we purchased the software now known as DATATRAK EDC® from PadCom Clinical Research. DATATRAK EDC® was developed to provide clinical research data to sponsors of clinical research trials faster and more efficiently than other forms of information-processing. Since the purchase of DATATRAK EDC®, we have devoted the majority of our efforts to developing and improving the EDC technology employed by this software.

The DATATRAK EDC® software and its earlier versions have supported many international clinical studies encompassing thousands of clinical research sites and tens of thousands of patients in over 46 countries. Our product suite has been utilized in some aspect of the clinical development of 14 separate drugs that have received regulatory approval from either the United States Food and Drug Administration or counterpart European bodies.

We were incorporated under the laws of the state of Ohio in July 1991. Our principal executive offices are located at 6150 Parkland Boulevard, Mayfield Heights, Ohio 44124. Our telephone number at that address is (440) 443-0082. We also have an office in Bonn, Germany.

**Recent Developments**

In December 2004, we received net proceeds of approximately \$4.4 million in connection with the consummation of a private placement of 486,313 of our common shares at a purchase price of \$9.50 per share. The terms of this financing included the issuance of three-year warrants to purchase a total of 72,948 common shares at \$14.40 per share to the investors in the private placement and the issuance of three-year warrants to purchase a total



## **Table of Contents**

of 21,316 common shares at \$14.40 per share to a placement agent for the private placement. These 580,577 common shares represent, assuming issuance of the 94,264 common shares underlying the warrants, 8.7% of our outstanding common shares. We expect to use the proceeds of the private placement to expand our worldwide marketing and sales efforts, continue investing in software development and for other general working capital purposes.

By its terms, the share purchase agreement, dated as of December 23, 2004, prohibits us from selling any of our common shares, during the period ending ninety days after December 27, 2004, at a price per common share of less than \$9.50, without paying the selling shareholders an amount equal to the difference between \$9.50 and the subsequent selling price, multiplied by the number of our common shares that each selling shareholder purchased in the December 2004 private placement. In addition to making a series of standard representations and warranties to the selling shareholders, we agreed to register the common shares which certain selling shareholders purchased pursuant to the share purchase agreement, dated as of December 23, 2004.

In December 2004, we entered into an alliance pursuant to which the Company and SAS Institute Inc. ( SAS ) will make a joint offering to customers to gather and analyze clinical trial data. During the initial two-year term of the alliance, we are obligated to make an aggregate of \$650,000 in fixed payments to SAS, for among other things, access to the SAS® Drug Development software. These fixed payments will allow us to make certain SAS software available to our customers during the initial term of the alliance. We are also entitled to provide similar use of the SAS software to our customers during a third option year upon the payment of a \$200,000 fixed fee. We will charge fees to our customers that utilize the SAS software that will allow us to recoup some or all of the fixed fees payable to SAS.

## **USE OF PROCEEDS**

All of the common shares offered under this prospectus are being sold by the selling shareholders. We will not receive any of the proceeds from the sale of these common shares.

## **THE SELLING SHAREHOLDERS**

The following table contains information with respect to the number of our common shares owned or issuable upon the exercise of warrants owned by each of the selling shareholders as of December 23, 2004. None of the selling shareholders has, or had, any position, office or other material relationship with us or any of our affiliates beyond their investment in or receipt of our securities, except for Robert R. Blakely, Scott R. Griffith and Jesse B. Shel mire, who are principals of Stonegate Securities, Inc., the placement agent for the private placement.

We have filed with the Commission a registration statement, of which this prospectus is a part, with respect to the resale of our common shares from time to time, under Rule 415 under the Securities Act of 1933, in the over-the-counter market, in privately negotiated transactions, in underwritten offerings or by a combination of these methods for sale. We have agreed to keep this registration statement effective until all of the common shares purchased pursuant to the share purchase agreement, dated as of December 23, 2004, and all of the common shares issuable upon the exercise of warrants issued pursuant to the share purchase agreement, dated as of December 23, 2004, have either (i) become eligible for resale under Rule 144(k) under the Securities Act or (ii) have been sold pursuant to the registration statement or Rule 144 or any other rule of similar effect.

The following table is prepared based on information supplied to us by the selling shareholders. Although we have assumed for purposes of the table below that the selling shareholders will sell all of the shares offered by this prospectus, because the selling shareholders may offer from time to time all or some of their shares covered under this prospectus, or in another permitted manner, no assurances can be given as to the actual number of shares that will be

resold by the selling shareholders or that will be held by the selling shareholders after completion of the resales. In addition, the selling shareholders may have sold, transferred or otherwise disposed of the common shares or the warrants in transactions exempt from the registration requirements of the Securities Act since the date the selling shareholders provided the information regarding their securities holdings. Information concerning the selling shareholders may change from time to time and changed information will be presented in a supplement to this prospectus if and when necessary and required. Except as described above, there are currently no agreements, arrangements or understandings with respect to the resale of any of the shares covered by this prospectus.

**Table of Contents**

The common shares offered by this prospectus may be offered from time to time by the persons or entities named below:

| Name of Selling Shareholder                                    | Shares Beneficially Owned<br>Prior to the Offering |                                  |         | Number<br>of<br>Shares<br>Offered | Shares Beneficially Owned<br>After the Offering(1) |                                  |         |
|--|--|----------------------------------|---------|-----------------------------------|--|----------------------------------|---------|
|  | Number   | Shares<br>Underlying<br>Warrants | Percent |                                   | Number   | Shares<br>Underlying<br>Warrants | Percent |
| Alpha Capital<br>Aktiengesellschaft(2)                         | 52,631   | 7,895                            | *       | 60,526                            | 0  | 0                                | *       |
| Robert R. Blakely(3)   |  | 7,106                            | *       | 7,106                             | 0  | 0                                | *       |
| Capital Ventures International<br>(4)                          | 78,947   | 11,842                           | 1.4     | 90,789                            | 0  | 0                                | *       |
| Fidelity Securities Fund: Fidelity<br>Small Cap Growth Fund(5) | 12,200   | 1,500                            | *       | 11,500                            | 2,200  | 0                                | *       |
| GSSF Master Fund, LP(6)  | 52,631   | 7,895                            | *       | 60,526                            | 0  | 0                                | *       |
| Gryphon Master Fund, L.P.(6)                                   | 52,631   | 7,895                            | *       | 60,526                            | 0  | 0                                | *       |
| Scott R. Griffith(3)   |  | 7,105                            | *       | 7,105                             | 0  | 0                                | *       |
| Midsummer Investment, Ltd.(7)                                  | 105,263  | 15,789                           | 1.8%    | 121,052                           | 0  | 0                                | *       |
| Jesse B. Shel mire(3)  |  | 7,105                            | *       | 7,105                             | 0  | 0                                | *       |
| Select Contrarian Value Partners,<br>L.P.(8)                   | 164,287  | 7,500                            | 2.6%    | 57,500                            | 114,287  | 0                                | 1.7%    |
| TCMP <sup>3</sup> Partners(9)                                  | 42,105   | 6,316                            | *       | 48,421                            | 0  | 0                                | *       |
| Truk International Fund, LP(10)                                | 2,526  | 379                              | *       | 2,905                             | 0  | 0                                | *       |
| Truk Opportunity Fund, LLC(10)                                 | 39,579   | 5,937                            | *       | 45,516                            | 0  | 0                                | *       |

\* Indicates less than 1%.

(1) Assumes all of the common shares registered are sold.

(2) Konrad Ackerman and Rainer Posch exercise voting and/or dispositive power over the securities held by Alpha Capital Aktiengesellschaft.

(3) Robert R. Blakely, Scott R. Griffith and Jesse B. Shel mire are principals of Stonegate Securities, Inc., the placement agent for the private placement.

(4) Heights Capital Management, Inc., the authorized agent of Capital Ventures International, has discretionary authority to vote and dispose of the securities held by Capital Ventures International and may be deemed to be the beneficial owner of those securities. Martin Kobinger, in his capacity as President of Heights Capital Management, Inc., may also be deemed to have investment discretion and voting power over the securities held by Capital Venture International. Mr. Kobinger disclaims any such beneficial ownership of the securities.

(5) Fidelity Securities Fund: Fidelity Small Cap Growth Fund is a registered investment fund (the Fund) advised by Fidelity Management & Research Company (FMR Co.), a registered investment adviser under the Investment Advisers Act of 1940, as amended. FMR Co., 82 Devonshire Street, Boston, Massachusetts 02109, a wholly-owned subsidiary of FMR Corp. and an investment adviser registered under Section 203 of the Investment Advisers Act of

1940, is the beneficial owner of the securities purchased by the Fund that are covered by this registration statement and a total of 602,545 of our common shares, as a result of acting as investment adviser to various investment companies (together with the Fund, the Funds ) registered under Section 8 of the Investment Company Act of 1940. Edward C. Johnson 3d, FMR Corp., through its control of FMR Co., and the Funds each have sole power to dispose of the securities purchased by the Fund that are covered by this registration statement and a total of 602,545 of our common shares owned by the Funds. Neither FMR Corp. nor Edward C. Johnson 3d, Chairman of FMR Corp., has the sole power to vote or direct the voting of the securities owned directly by the Fund, which power resides with the Fund s Board of Trustees.

(6) E.B. Lyon IV exercises voting and/or dispositive power over the securities held by GSSF Master Fund, LP and Gryphon Master Fund, L.P.

(7) Midsummer Capital, LLC, as the general partner of the selling shareholder, has voting and investment power with respect to the securities reported in the table for this selling shareholder. Accordingly, Midsummer Capital, LLC may be deemed a beneficial owner of our securities. Midsummer Investment, Ltd. is a private investment limited partnership.

(8) Kaizen Management, L.P., as the general partner of the selling shareholder, has voting and investment power with respect to the securities reported in the table for this selling shareholder. Accordingly, Kaizen Management, L.P. may be deemed a beneficial owner of our securities. Kaizen Capital, LLC is the general partner of Kaizen Management, L.P. David Berry is the sole member of Kaizen Capital LLC and may be deemed a beneficial owner of our securities. Select Contrarian Value Partners, L.P. is a private investment limited partnership. Mr. Berry disclaims any beneficial ownership of the securities..

(9) Steven Slawson and Walter Schenker, principals of TCMP<sup>3</sup> Partners, have voting and investment control over the securities held by TCMP<sup>3</sup> Partners.

(10) Michael E. Fein and Stephen E. Saltzstein, as principals of Atoll Asset Management, LLC, the managing member of Truk Opportunity Fund, LLC, and general partner of Truk International Fund, LP, exercise investment and voting control over the securities owned by these selling shareholders. Both Mr. Fein and Mr. Saltzstein disclaim beneficial ownership of the securities owned by these selling shareholders.

## **PLAN OF DISTRIBUTION**

We are registering all 580,577 common shares on behalf of the selling shareholders. The selling

**Table of Contents**

shareholders named in the table above or pledgees, donees, transferees or other successors-in-interest selling shares received from a named selling shareholder after the date of this prospectus may sell the shares from time to time. The selling shareholders may also decide not to sell all the shares they are allowed to sell under this prospectus. The sales may be made on one or more exchanges or in the over-the-counter market or otherwise, at prices and at terms then prevailing or at prices related to the then current market price, in negotiated transactions or any other legally available means. The selling shareholders may effect such transactions by selling the shares to or through broker-dealers. The selling shareholders have advised us that they have not entered into any agreements, understandings or arrangements with any underwriters or broker-dealers regarding the sale of their common shares, nor is there an underwriter or coordinating broker acting in connection with proposed sales of common shares by the selling shareholders. Our common shares may be sold by one or more of, or a combination of, the following:

a cross trade or a block trade in which a broker or dealer will attempt to sell the common shares as agent but may position and resell a portion of the block as principal to facilitate the transaction,

purchases by a broker or dealer as principal and resale by such broker or dealer for its account pursuant to this prospectus,

an exchange distribution in accordance with the rules of such exchange,

ordinary brokerage transactions and transactions in which the broker solicits purchasers,

to or through Market Makers or into an existing market for the shares, and

in privately negotiated transactions.

In addition, any common shares covered by this prospectus which qualify for sale pursuant to Rule 144 may be sold under Rule 144 rather than pursuant to this prospectus.

The selling shareholders may enter into hedging transactions with broker-dealers in connection with distributions of our common shares or otherwise. In such transactions, broker-dealers may engage in short sales of the shares in the course of hedging the positions they assume with selling shareholders. The selling shareholders also may sell shares short and redeliver our common shares to close out such short positions. The selling shareholders may enter into option or other transactions with broker-dealers which require the delivery to the broker-dealer of our common shares. The broker-dealer may then resell or otherwise transfer such shares pursuant to this prospectus. The selling shareholders also may loan or pledge the shares to a broker-dealer. The broker-dealer may sell our common shares so loaned, or upon a default the broker-dealer may sell the pledged shares pursuant to this prospectus.

The selling shareholders may effect transactions by selling common shares directly to purchasers or to or through broker-dealers, which may act as agents or principals. Those broker-dealers may receive compensation in the form of discounts, concessions or commissions from the selling shareholders and/or the purchasers of shares for whom those broker-dealers may act as agents or to whom they sell as principal, or both (which compensation as to a particular broker-dealer might be in excess of customary commissions). Compensation as to a particular broker-dealer might be in excess of customary commissions and will be in amounts to be negotiated in connection with our common shares.

The selling shareholders and any broker-dealers that act in connection with the sale of common shares might be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act, and any commissions received by those broker-dealers and any profit on the resale of the common shares sold by them while acting as principals might be deemed to be underwriting discounts or commissions under the Securities Act.

Because the selling shareholders may be deemed to be underwriters within the meaning of Section 2(11) of the Securities Act, the selling shareholders will be subject to the prospectus delivery requirements of the Securities Act.

**Table of Contents**

Under applicable rules and regulations under the Securities Exchange Act of 1934, any person engaged in the distribution of our common shares may not simultaneously engage in market-making activities with respect to our common shares for a period of two business days prior to the commencement of such distribution. In addition, each selling shareholder will be subject to applicable provisions of the Exchange Act and the associated rules and regulations under the Exchange Act, including Regulation M, which provisions may limit the timing of purchases and sales of our common shares by the selling shareholders. We will make copies of this prospectus available to the selling shareholders and have informed them of the need for delivery of copies of this prospectus to purchasers at or prior to the time of any sale of our common shares.

We will file a supplement to this prospectus, if required, pursuant to Rule 424(b) under the Securities Act upon being notified by a selling shareholder that any material arrangement has been entered into with a broker-dealer for the sale of shares through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker or dealer. Such supplement will disclose:

the name of each such selling shareholder and of the participating broker-dealer(s),

the number of shares involved,

the price at which such shares were sold,

the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable,

that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and

other facts material to the transaction.

We retained Stonegate Securities, Inc., a registered broker-dealer, as a placement agent to identify for us certain prospective purchasers to participate in the offering pursuant to a placement agent agreement. The placement agent was only required to act on a best efforts basis and had no obligation to purchase any of the securities offered in the offering.

As compensation for services rendered by the placement agent in connection with the offering, we agreed to pay the placement agent a fee of six percent of the gross proceeds from the sale of securities sold to those purchasers that the placement agent identified. We also agreed to issue warrants to purchase an amount of securities equal to five percent of the amount of securities sold to those purchasers that the placement agent identified. The warrants are for a period of three years at an exercise price per share of \$14.40. The placement agent and/or its respective agents and the number of warrants they have received respectively are referenced above in the selling shareholders table. Finally, we have agreed to reimburse the placement agent for certain of its reasonable out-of-pocket expenses in connection with their performance under the placement agent agreement.

Pursuant to the terms of the placement agent agreement, we agreed to indemnify and hold the placement agent harmless from and against any and all losses, claims, damages or liabilities (or actions, including securityholder actions, in respect thereof) related to or arising out of the placement agent's engagement (except by reason of the bad faith, gross negligence or willful misconduct of any such placement agent), and to reimburse the placement agent for all reasonable expenses in connection with investigating, preparing for or defending any such action or claim, whether or not in connection with pending or threatened litigation in which such placement agent may be a party.

Pursuant to the share purchase agreement, dated as of December 23, 2004, we have filed the registration statement, of which this prospectus is a part, with respect to the sale of certain selling shareholders' common shares. We have

agreed, subject to certain exceptions, to indemnify and hold harmless each of the selling shareholders against any losses, claims, damages, liabilities or expenses, joint or several, to which such selling shareholder may become subject, insofar as such losses, claims, damages, liabilities or expenses arise out of a breach of the share purchase agreement or are based upon any untrue statement, alleged untrue statement, omission or alleged omission



**Table of Contents**

of any material fact contained in the registration statement, including the prospectus, financial statements and schedules, and all other documents filed as a part thereof, or any amendment or supplement thereto. We have agreed to pay all fees and expenses incurred by us in connection with the registration of the common shares pursuant to the share purchase agreement, dated as of December 23, 2004. We have also agreed to pay for the reasonable legal and other out-of-pocket expenses actually incurred by the purchasers in connection with the negotiation, execution and consummation of the share purchase agreement, dated as of December 23, 2004, and the agreements and transactions contemplated by that agreement, in an amount not to exceed \$15,000 in the aggregate. All other expenses and fees associated with the sale of the common shares by the selling shareholders will be paid by the selling shareholders.

**LEGAL MATTERS**

The validity of the issuance of the common shares offered by this prospectus will be passed upon by Calfee, Halter & Griswold LLP, Cleveland, Ohio.

**EXPERTS**

Ernst & Young LLP, independent registered public accounting firm, have audited our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2003, as set forth in their report, which is incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on Ernst & Young LLP's report, given on their authority as experts in accounting and auditing.

**WHERE YOU CAN FIND MORE INFORMATION**

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy any document that we file at the Commission's Public Reference Room at 450 Fifth Street, N.W., Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the Public Reference Room. Our filings with the Commission are also available to the public through the Commission's Internet site at <http://www.sec.gov>.

We have filed a registration statement on Form S-3 with the Commission. This prospectus is a part of the registration statement and does not contain all of the information in the registration statement. Wherever a reference is made in this prospectus to a contract or other document, please be aware that the reference is not necessarily complete and that you should refer to the exhibits that are a part of the registration statement for a copy of the contract or other document. You may review a copy of the registration statement at the Commission's Public Reference Room in Washington, D.C., as well as through the Commission's Internet site.

**INCORPORATION BY REFERENCE**

The Commission allows us to incorporate by reference the information we file with the Commission, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is an important part of this prospectus.

Information that we file in the future with the Commission and incorporate by reference in this prospectus will automatically update and replace this information. We incorporate by reference the documents listed below and any

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future filings made by us with the Commission under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act, other than information furnished in any Current Report on Form 8-K pursuant to items 2.02, 7.01 or 9.01 of Form 8-K, if the filings are made before the time that all of the common shares are sold in this offering.

our annual report on Form 10-K for the year ended December 31, 2003,

our quarterly report on Form 10-Q for the quarter ended March 31, 2004,

our quarterly report on Form 10-Q for the quarter ended June 30, 2004,

**Table of Contents**

our quarterly report on Form 10-Q for the quarter ended September 30, 2004,

our current reports on Form 8-K or 8-K/A filed on December 28, 2004, January 3, 2005 and January 12, 2005

our registration statement on Form 8-A, filed on May 10, 1996, describing our common shares, and

our registration statement on Form 8-A, filed on September 19, 1997, describing the rights to purchase our common shares.

You may request a copy of these filings at no cost by writing or telephoning us at the following address:

DATATRAK International, Inc.  
6150 Parkland Boulevard  
Mayfield Heights, Ohio 44124  
Attention: Mr. Terry C. Black  
(440) 443-0082 x110

You should rely only on the information incorporated by reference or provided in this prospectus. We have not authorized anyone else to provide you with different information. We are not making an offer of the common shares in any state where the offer is not permitted. You should not assume that the information in this prospectus is accurate as of any date other than the date of this prospectus or the date of the documents incorporated by reference in this prospectus.

**Table of Contents****PART II****INFORMATION NOT REQUIRED IN PROSPECTUS****Item 14. Other Expenses of Issuance and Distribution**

The registrant will bear the entire cost of the estimated expenses, as set forth in the following table, in connection with the distribution of the securities covered by this registration statement.

|                              |               |
|------------------------------|---------------|
| SEC registration fee         | \$ 725        |
| Legal fees and expenses      | 10,000        |
| Accounting fees and expenses | 21,000        |
| Nasdaq fees                  | 5,000         |
| Printing expenses            | 1,000         |
| Miscellaneous                | 1,000         |
| <br>                         |               |
| Total                        | <br>\$ 38,725 |

The registrant will be responsible for the payment of any additional expenses in connection with the preparation and filing of this registration statement.

**Item 15. Indemnification of Directors and Officers**

Under Ohio law, Ohio corporations are authorized to indemnify directors, officers, employees and agents within prescribed limits and must indemnify them under certain circumstances. Ohio law does not provide statutory authorization for a corporation to indemnify directors, officers, employees and agents for settlements, fines or judgments in the context of derivative suits. Ohio law does provide, however, that directors (but not officers, employees and agents) are entitled to mandatory advancement of expenses, including attorneys' fees, incurred in defending any action, including derivative actions, brought against the director provided that the director agrees to cooperate with the corporation concerning the matter and repay the amount advanced if it is proved by clear and convincing evidence that his act or failure to act was done with deliberate intent to cause injury to the corporation or with reckless disregard to the corporation's best interests.

Ohio law does not authorize payment of judgments to a director, officer, employee or agent after a finding of negligence or misconduct in a derivative suit absent a court order. Indemnification is required, however, to the extent such person succeeds on the merits. In all other cases, if a director, officer, employee or agent acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, indemnification is discretionary, except as otherwise provided by a corporation's articles of incorporation, code of regulations or by contract, except with respect to the advancement of expenses of directors.

Under Ohio law, a director is not liable for monetary damages unless it is proved by clear and convincing evidence that his action or failure to act was undertaken with deliberate intent to cause injury to the corporation or with reckless disregard for the best interests of the corporation. There is no comparable provision, however, limiting the liability of officers, employees or agents of a corporation. The statutory right to indemnification is not exclusive in Ohio, and Ohio corporations may, among other things, procure insurance for such persons.

The registrant's Third Amended and Restated Code of Regulations provides that the registrant will indemnify to the fullest extent permitted by law any director or officer made or threatened to be made a party to any action, suit or proceeding by reason of the fact that he is or was a director or officer of the registrant, or is or was serving as a director, officer, partner, trustee, employee or agent at the request of the registrant of another corporation, partnership, joint venture, trust or other enterprise, against all expense, liability and loss, including attorneys' fees, judgments, fines, excise taxes or penalties and amounts paid or to be paid in settlement, reasonably incurred or suffered by such person in connection therewith.

II-1

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## **Table of Contents**

Under the terms of the registrant's directors' and officers' liability and company reimbursement insurance policy, directors and officers of the registrant are insured against certain liabilities, including liabilities arising under the Securities Act of 1933.

### **Item 16. Exhibits**

See Exhibit Index.

### **Item 17. Undertakings**

(a) The undersigned registrant hereby undertakes:

(1) to file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Securities and Exchange Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement;

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

*provided, however*, that paragraphs (a)(1)(i) and (a)(1)(ii) do not apply if the registration statement is on Form S-3, Form S-8 or Form F-3, and the information required to be included in a post-effective amendment by those paragraphs is contained in periodic reports filed with or furnished to the Securities and Exchange Commission by the registrant pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the

II-2

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**Table of Contents**

registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.



**Table of Contents****SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933 the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Cleveland, state of Ohio, on this 12th day of January, 2005.

**DATATRAK INTERNATIONAL, INC.**

By: /s/ Jeffrey A. Green  
 Jeffrey A. Green  
 President and Chief Executive Officer

**POWER OF ATTORNEY**

Each person whose signature appears below hereby authorizes and appoints that Jeffrey A. Green, Terry C. Black, Thomas F. McKee, Arthur C. Hall III and Seth M. Jupin, be, and each of them hereby is, appointed as his or her attorney-in-fact to sign on his behalf individually and in the capacity stated below any and all amendments and post-effective amendments to this Registration Statement and any additional registration statement filed pursuant to Rule 462(b) under the Securities Act of 1933 in respect of an offering contemplated by this Registration Statement that his or her attorney-in-fact may deem necessary or appropriate.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities indicated on this 12th day of January, 2005.

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

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Mark J. Ratain

II-4

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**Table of Contents**

**EXHIBIT INDEX**

| <b>Exhibit<br/>Number</b> | <b>Description</b>  |
|---------------------------|---|
| 3.1                       | Sixth Amended and Restated Articles of Incorporation of the Company, filed on August 13, 2003 as Exhibit 3.1 to the Company's Form 10-Q for the quarter ended June 30, 2003 (Commission File No. 000-20699), and incorporated herein by reference.                                |
| 3.2                       | Third Amended and Restated Code of Regulations of the Company, effective May 2, 1996, filed on March 27, 2003 as Exhibit 3.4 to the Company's Form 10-K for the year ended December 31, 2002 (Commission File No. 000-20699), and incorporated herein by reference.               |
| 3.3                       | Amendment to Third Amended and Restated Code of Regulations of the Company, effective June 4, 2002, filed on March 27, 2003 as Exhibit 3.5 to the Company's Form 10-K for the year ended December 31, 2002 (Commission File No. 000-20699), and incorporated herein by reference. |
| 3.4                       | Amendment to Third Amended and Restated Code of Regulations of the Company, effective June 3, 2003, filed on August 13, 2003 as Exhibit 3.4 to the Company's Form 10-Q for the quarter ended June 30, 2003 (Commission File No. 000-20699), and incorporated herein by reference. |
| 4.1                       | Specimen Certificate of the Company's Common Shares, without par value, filed on March 28, 2000 as Exhibit 4.1 to the Company's Form 10-K for the year ended December 31, 1999 (Commission File No. 000-20699), and incorporated herein by reference.                             |
| 4.2                       | Rights Agreement, dated September 2, 1997, between the Company and National City Bank, as Rights Agent, filed on September 19, 1997 as Exhibit 1 to Form 8-A, and incorporated herein by reference.   |
| 5.1                       | Opinion of Calfee, Halter & Griswold LLP, as to the validity of the Company's Common Shares.*   |
| 23.1                      | Consent of Ernst & Young LLP, Independent Auditors.*  |
| 23.2                      | Consent of Calfee, Halter & Griswold LLP (included in Exhibit 5.1).   |

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\* Filed herewith.