IT&E INTERNATIONAL GROUP
Form 8-K/A
May 04, 2005

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549
AMENDMENT NO. 2 TO
FORM 8-K/A
CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 14, 2004

IT&E International Group
(Exact name of registrant specified in charter)

Nevada	0-50095	77-0436157
(State of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

505 Lomas Santa Fe Drive, Suite 200, Solana Beach, CA	92075
(Address of principal executive offices)	(zip code)

Issuer's telephone number: (858) 366-0970

Not applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

[_] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
[_] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
[_] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
[_] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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ITEM 2.01 ACQUISITION OR DISPOSITION OF ASSETS.

Set forth below is certain information concerning the principal terms of the Merger and the business of the Registrant and IT&E.

Principal Terms of the Reverse Acquisition and Plan of Merger

At the Effective Time of the Merger (as defined in the Acquisition and Plan of Merger Agreement), Merger Sub acquired 100% of the outstanding shares of IT&E. The separate existence of Merger Sub ceased, and IT&E continued as a subsidiary of the Parent corporation ("CTAL"), under the current name of the Registrant. The Certificate of Incorporation of the Parent in effect immediately prior to the Effective Time, remains the Certificate of Incorporation of the Parent. The directors and officers of IT&E at the Effective Time of the Merger became the directors and officers of the Parent.

Each share of IT&E common stock (an aggregate of 481,500 shares) was converted into one share of the Registrant's common stock in the Reverse Acquisition, an exchange ratio of 1:18.7 (the "Exchange Ratio") for 11,000,000 common shares and 2,820,000 preferred shares, which can be converted for common shares at a ten-for-one ratio, after they are held for two years.

Description of the Registrant

The Registrant, a Nevada corporation, was incorporated on April 22, 2002. At the, Effective Time of the Merger, the principal business objective and focus of the Registrant was the "lifesciences" industry, which includes helping physician researchers recruit appropriate patients to participate in specific clinical research trials sponsored by the pharmaceutical industry.

An objective of the Registrant was to identify and acquire a business which writes protocols for clinical research studies. CTAL recruits patients for clinical studies and IT&E develops the protocols for these clinical studies. The two companies enhance each others operations. Prior to the Effective Time, Mr. Kamill Rohny and Dr. Eugene Boling were the directors of the Registrant. Mr. Rohny and Dr. Boling resigned as directors of the Registrant immediately after the Effective Time of the Merger. Mr. Rohny also resigned as an officer of the Registrant after the Effective Time of the Merger.

The shares of common stock of the Registrant are traded on the OTC Bulletin Board under the symbol "CTAL."

Following the Merger, the stockholders of IT&E became stockholders of the Registrant. All executive officers of IT&E became executive officers of the Registrant, and the Board of Directors of IT&E became the Board of Directors of the Registrant. Upon the consummation of the Merger, IT&E became a wholly-owned subsidiary of the Registrant, and the Registrant will change its name to: IT&E International Group.

DESCRIPTION OF BUSINESS

General

We are a life sciences organization focused on providing our clients with solutions to complex needs in clinical research and regulatory compliance. We serve a variety of clients, including those in the private industry, public institutions, research facilities and the government. By focusing on specialized practice areas in regulatory compliance, clinical research, and international development of global health and advanced technology research, we are able to offer solutions with one common goal in mind, to improve the human condition by delivering our solutions to the global community.

We were incorporated in Nevada in 2002 as Clinical Trials Assistance Corporation. In April 2004, we merged with IT&E International, Inc. and changed our name to IT&E International Group.

IT&E's Business and Operations

IT & E International, Inc. is a provider of a broad range of services to the Life Sciences Industries. We primarily provide our clients with solutions to complex needs in clinical research and regulatory compliance.

We provide regulatory compliance services to pharmaceutical, biotech, healthcare and other life science companies by providing to them the expertise to evaluate, structure, implement and maintain effective quality programs and processes that ensure compliance with applicable FDA regulations. We offer a diverse, all encompassing solution for the validation and compliance of quality systems, laboratory and manufacturing processes, clinical data systems, laboratory automation, content management, electronic document management, and a complete solution for facilities, utilities and equipment validation and compliance.

We also offer a full suite of clinical trial support services, such as patient and investigator recruitment, biostatistical analysis, data management, data entry and verification and regulatory affairs services. In data management, we provide case report form design, protocol development, data entry and verification, full tracking and audit trail documentation, adverse event reporting and FDA submission. Our biostatistical analysis group provides data mining studies, database design, representation at FDA and other regulatory meetings, and additional specialized biostatistical analysis.

Program Management and Outsourcing

IT&E's clients rely on us to protect the integrity of their data and provide for a secure environment for successful delivery. Said differently, to protect the integrity of systems in a validated state means that when a system is validated per the rules and regulations of the FDA, any subsequent change or modification to those systems must also be validated in the same manner in strict compliance with FDA Rules & Regulations. Our program managers

consist of senior medical professionals with specific expertise in designing, developing, and managing Phase I through Phase III and Post-Marketing Clinical Trials. Program managers serve as liaisons between the numerous coordinating sites and individuals involved in the final completion of the project.

We offer a complete range of validation and compliance services from management consulting to protocol development and execution. We are dedicated to designing, developing and implementing practices that protect the integrity of the computerized systems and equipment used in health product research and manufacturing processes. IT&E We ensure that these systems are maintained in a validated state throughout their entire lifecycle by following documented protocols and standardized procedures. IT&E has the ability to deliver regulatory compliance services in the following fields:

- Guidelines Interpretation
- Planning & Strategy

- Corporate policies and procedures
- Methodology
- Independent Vendor Audits & Assessments
- SOP Generation and Revision
- Gap Analysis
- Risk Analysis - Business and Regulatory
- Remediation
- Training end users and program managers

IT&E provides services in the CSV, Part 11, Part 210/211, Part 58, Part 320, Part 820/QSR, GAMP4 as well as European and Asian standards. The standards referred to are generally accepted standards for good clinical practices, good manufacturing practices, good laboratory practices and overall good generally accepted practices established for the development of a new drug or medical device. These standards refer to practices and sections established by the FDA. Our validation and compliance team designs, develops and implements practices that protect the integrity of the computerized systems, equipment and facilities used in health product research and manufacturing processes. Further, we ensure that these systems are maintained in a validated state throughout their entire lifecycle by following documented protocols and standardized procedures. By analyzing market trends, continually reengineering our best practices, utilizing leading technology and keeping abreast of changes from the regulatory bodies, we are able to ensure a high degree of quality standards are being met.

In addition, we specialize in quality procedures, programs and management consulting in FDA regulated areas within the pharmaceutical and biotechnology industries including: audits, remediation, quality systems, and validation and qualification of processes, cleaning, environment, and computerized systems. We have developed and implemented several plant-wide systems in the pharmaceutical and biotechnology industries. Along with the strategic alliance, of a proprietary methodology, with Correlate & IBM, IT&E has developed and has access to an extensive database which includes formats and templates

to get projects off and running quicker and maximize the efficiency in development and the ensuing validation and compliance processes. We provide services focused around GxP compliance, validation and regulatory affairs for the life sciences industry, including the following:

- Computer Systems Validation (CSV)
- 21 CFR Part 210/211 - Good Manufacturing Practices
- 21 CFR Part 11 - Electronic Signatures and Electronic Records
- Several other FDA and EMEA regulated areas
- Computerized Systems Validation
- Cleaning Validation
- Facility, equipment and Utility Validation
- Sterilization and Sanitization Validation
- Process Validation

IT&E offers a complete solution for the clinical trials and clinical research industry, including:

Clinical Data Entry and Data Management

IT&E is capable of providing SAS (R) end-to-end solutions throughout every stage of a drug's lifecycle: from discovery, development, and through

commercialization. We focus on assessing, advising, and designing comprehensive systems solutions in the pharmaceutical, biotechnology, and medical devices industries. We provide leading and emerging pharmaceutical and biotechnology companies with project-based consulting services in the areas of Data Management (SAS(R) databases and Oracle(R) Clinical systems), Clinical Programming, Biostatistics, and Clinical Validation (GCP). The IT&E team of project/program managers bring an average of 10+ years of biopharma experience to their clients, as well as the tools, talent and strategies necessary to carry a project from conception to completion. IT&E's extensive database selects and employs project-specific analysts to provide constant monitoring of project scope, budget, and deliverables while utilizing the IT&E custom Project Tracking System to provide clients with real-time, comprehensive status reports.

Data Management

IT&E provides a full range of data management solutions, including SAS(R) databases and Oracle(R) Clinical, as well as web-based or conventional means of data capture. Following are some of the specific areas of expertise:

- SAS (R) databases - Major functions supported
- Datasets
- Case Report Form design and analysis
- Safety Information
- Data marts for Data mining
- Integrated Data Analysis Systems
- Data Validation Specifications
- Database Design, install, and upgrade
- Data Quality Assurance
- Global Database Integration
- Oracle(R) Clinical - Major functions supported
- Define and manage a Clinical Study (Protocol)
- Define data elements to be collected in a Clinical study
- Define and generate data entry screens
- Define edit checks to be applied to the data
- Validation and derivation procedures [data]
- Collect and manage the data
- Data Extract to SAS for analysis

Clinical Programming

IT&E provides accurate and reliable programming to support regulatory submissions and clinical study reports. Because of the extensive experience of the IT&E consultants, we are able to optimize the flow of valuable scientific and operational data thereby assisting our clients to get their products to market faster.

Biostatistics

IT&E's biostatisticians focus on the delivery of quality design consulting and statistical analyses for clients engaged in complex clinical studies. This team delivers superior results for targeted summaries of key findings within the regulatory finding process, as well as producing creative scientific presentations. Some of the areas of expertise are as follows:

- Clinical Study Design
- Estimation of sample size
- Trial duration
- Structuring of treatment comparisons
- Definition of key endpoints
- Number and timing of analyses
- Precise interpretations of results
- Data displays and interpretations
- Clinical development programs
- ISS/ISE preparation
- Prepare integrated clinical/statistical reports
- Design tables and graphics
- Analysis planning and preparation
- Summary of statistical methodologies
- Support submissions to regulatory agencies (FDA)

Clinical Validation (GCP)

IT&E's clinical validation practice goes hand-in-hand with the efforts of the Compliance Group. Our regulatory and safety services must compliment our clients' drug development process from beginning to end. The IT&E and Client Partnership is truly a "Partnership That Works". By partnering with our clients to design a study that combines an understanding of the regulatory environment and current FDA regulations, we ensure a smooth and efficient development cycle. IT&E has designed its own Clinical Validation Methodology for the enterprise that is designed to satisfy regulated business practices and procedures that involves multiple groups within the organization (users, systems, database administrators, and other support staff).

Typically, the IT&E Validation Plan describes the system and scope, outlines the schedule and resources (GANTT), defines the testing strategy (and SOPs), and describes the deliverables that will document the validation process. The steps are as follows:

- Validation Plan Preparation
- System Inventory Preparation
- Preparing the work plan using the 5C's: System Classification, Complexity, Control, Compliance, Criticality
- Preparing Individual System Profiles & Gap Analysis
- Global Technological & Procedural Gap Matrix Preparation
- Preparing, Monitoring and Executing various Validation Protocols including Design Qualifications (DQ), Installation Qualifications (IQ), Operational Qualifications, (OQ), Performance Qualifications (PQ), Equipment Qualifications (EQ)
- Risk Analysis Matrix (The validation effort is premised on a determination

of risk and after addressing the 5 C's can we ascertain what level of design documentation is sufficient for a specified system)

Competition

The drug and medical device development outsourcing industry consists of hundreds of smaller, limited-service providers and a number of full-service development companies. The industry continues to experience consolidation and, in recent years, a group of large, full-service competitors has emerged. This trend of industry consolidation appears to have created greater competition among the larger companies for clients and acquisition candidates. Specifically, in the regulatory compliance area, we compete against such companies as RCM Technologies, Teratec, and Comsys (Venturi Partners), in the clinical services area, we compete against Covance, Charles River/Inversek, SFBC International, Covalent, Icon, Kendle, and Parexel.

In addition to competing with a number of full-service companies, IT&E also competes against some medium-sized companies, in-house research and development departments of pharmaceutical and biotechnology companies, as well as universities and teaching hospitals. In addition, the industry has few barriers to entry. Newer, smaller entities with specialty focuses, such as those aligned to a specific disease or therapeutic area, compete aggressively against larger companies for clients. Increased competition might lead to price and other forms of competition that might adversely affect our operating results.

IT&E competes on the basis of a number of factors, including on-time quality performance, expertise and experience in specific therapeutic areas, scope of service offerings, price, strengths in various geographic markets, technological expertise and systems, data management capabilities for time savings with data integrity, ability to acquire, process, analyze and report data in a time-saving accurate manner, ability to manage large-scale clinical trials both domestically and internationally, and expertise and experience in healthcare economics. There are no assurances that the IT&E will be able to compete favorability in these areas.

For specialty areas such as laboratory and manufacturing validation, medical communications, and protocol development, IT&E competes in a market that has a myriad of niche providers. For the most part, these niche providers offer specialty services and products with a focus on a specific geographic region, a particular service or function and/or a specific stage or phase of drug development. By contrast, IT&E provides its services across functional areas. IT&E competes based on its scientific and technical expertise, experience and qualifications of professional staff, quality of services, and ability to deliver finished products to the client's specifications. The outsourced preclinical research industry consists of a number of large providers and numerous smaller niche companies. As such, there is significant competition for these opportunities, and IT&E success will depend on our ability to identify and competitively bid for risk-sharing programs that are likely to be productive.

Government Regulation

IT&E's clients are subject to extensive regulations by government agencies. Consequently, the services IT&E provides for these clients must comply with

relevant laws and regulations.

Prior to commencing human clinical trials in the United States, a company developing a new drug must file an IND with the FDA. The IND must include information about animal toxicity and distribution studies, manufacturing and control data, stability data and a detailed plan, or study protocol, for the proposed clinical trial of the drug or biologic in humans. If the FDA does not object within 30 days after the IND is filed, human clinical trials may begin. The study protocol will also be reviewed and approved by the institutional review board, or IRB, in each institution in which a study is conducted, and the IRB may impose additional requirements on the way in which the study is conducted in its institution.

Human trials usually start on a small scale to assess safety and then expand to larger trials to test efficacy along with safety in the target population. The trials are generally conducted in three phases, which sometimes overlap, although the FDA may require a fourth phase as a condition of approval. After the successful completion of the first three clinical phases, a company requests approval for marketing its product by submitting a new drug application, or NDA. The NDA is a comprehensive, multi-volume filing that includes, among other things, the results of all pre-clinical and clinical studies, information about how the product will be manufactured and tested, additional stability data and proposed labeling. The FDA's review can last from six months to many years, with the average review lasting 18 months. Once the NDA is approved, the product may be marketed in the United States subject to any conditions imposed by the FDA.

IT&E must conform to regulatory requirements that are designed to ensure the quality and integrity of the testing process. To help ensure compliance with these regulations, IT&E has established quality assurance at our laboratory facilities to monitor ongoing compliance by auditing test data and conducting regular inspections of testing procedures and our laboratory facilities. IT & E is in compliance with all rules, regulations and laws applicable to IT & E. To the best of our knowledge, we have not been out of compliance in the last three years.

Facilities

IT&E International's headquarters are located at: 31 N. Second Street, Suite 250 San Jose, California 95113. The Company also has offices at:

6165 Greenwich Drive, Suite 170
San Diego, California 92122

One East Broward Boulevard, Suite 609
Fort Lauderdale, Florida 33301

222 S. Riverside Plaza, Suite 860
Chicago, Illinois 60606

203 East Main Street
Middleburg, Pennsylvania 17842

1050 17th Street, NW
Suite 600
Washington, DC 20036

We do not maintain any facilities needing FDA certification or state certification.

Employees

IT&E employs approximately 100 employees. These employees represent the following employment mix for the company: 10% administration, 7% recruiting, 5% sales, and 78% contract service providers. Additionally we utilize the services of approximately 30 outside consultants who work as independent contractors for IT&E.

Risk Factors

The actual results of the combined company may differ materially from those anticipated in these forward-looking statements. The Registrant and IT&E will operate as a combined company in a market environment that is difficult to predict and that involves significant risks and uncertainties, many of which will be beyond the combined company's control. Additional risks and uncertainties not presently known, or that are not currently believed to be important, if they materialize, also may adversely affect the combined company.

Risks Related to IT&E's Business

IT&E's success depends in part on its ability to expand the content of its existing business and build a wider customer a cost-effective manner and on a timely basis. The expansion of IT&E's existing business and its development of new programs may not be accepted by its customers. Even if IT&E is able to develop acceptable new business models, it may not be able to introduce these new business models as quickly as its customers require or as quickly as its competitors.

Failure to adequately respond to changes in market needs and technologies could have a material adverse effect on IT&E's business and results of operations.

Capacity constraints or system disruptions to IT&E's business models could damage the customer image reputation of IT&E and limit its ability to attract

and retain customers in the pharmaceutical and biotechnology industry.

Risk related to Government Regulations

The industry standards for the conduct of clinical research and development studies are embodied in the regulations for Good Clinical Practice ("GCP"). The FDA and other regulatory authorities require that results of clinical trials that are submitted to such authorities be based on studies conducted in accordance with GCP. These regulations require that IT&E, among other things: comply with specific requirements governing the selection of qualified investigators:

- obtain specific written commitments from the investigators;
- verify that appropriate patient informed consent is obtained;
- monitor the validity and accuracy of data;
- instruct investigators and studies staff to maintain records and reports;
- permit appropriate governmental authorities access to data for their review.

IT&E must also maintain reports for each study for specified periods for auditing by the study sponsor and by the FDA. IT&E is liable to its clients for any failure to conduct their studies properly according to the agreed upon protocol and contract. If IT&E fails to conduct a study properly in ccordance with the agreed upon procedures, IT&E may have to repeat the study at its expense, reimburse the client for the cost of the study and pay additional damages.

Changes in trends in the pharmaceutical and biotechnology industries could adversely affect IT&E's operating results.

Industry trends and economic factors that affect the pharmaceutical and biotechnology industry can also adversely affect IT&E's business. For example, the practice of many companies in these industries has been to hire companies like IT&E to conduct development projects. If these industries reduce their tendency to outsource those projects, IT&E's operations, financial condition and growth rate could be materially and adversely affected. In the past several years, mergers and other factors in the pharmaceutical industry appear to have slowed decision-making by pharmaceutical companies and delayed drug development projects. Continuation or increases in these trends could have an ongoing adverse effect on IT&E's business. If future regulatory cost containment efforts limit the profits that can be derived on new drugs, the pharmaceutical and biotechnology customers might reduce their drug discovery and development spending, which could reduce IT&E's business.

IT&E's revenue depends on a small number of industries and clients.

IT&E provides services to the pharmaceutical and biotechnology industries and IT&E's revenue is highly dependent on expenditures by clients in these industries. Currently, approximately 25% of IT&E's business is derived from one customer. IT&E's operations could materially suffer if their largest

customer hires a different supplier for services provided by IT&E. The loss of business from a significant client could have a material adverse effect on IT&E's results of operations.

The Registrant cannot predict IT&E's future capital needs, and may not be able to secure additional financing.

The Registrant will likely need to raise additional funds in the future to fund IT&E's operations, to expand its markets and product offerings, or to respond to competitive pressures or perceived opportunities. The Registrant cannot assure that additional financing will be available on favorable terms, or at all. If adequate funds are not available when required or on acceptable terms.

Future acquisitions or investments could disrupt IT&E's ongoing business, distract management and employees, increase expenses and adversely affect IT&E's business.

IT&E's management anticipates that a portion of any future growth of its business might be accomplished by acquiring existing businesses, products or technologies. The success of any acquisitions will depend upon, among other things, management's ability to integrate acquired personnel, operations, products and technologies into its organization effectively, to retain and motivate key personnel of acquired businesses and to retain their customers. In addition, IT&E might not be able to identify suitable acquisition opportunities or obtain any necessary financing on acceptable terms. Any future acquisitions could involve other risks, including the assumption of additional liabilities and expenses, issuances of potentially dilutive equity securities or interest-bearing debt, transaction costs, reduction in our stock price as a result of any of these or because of market reaction to a transaction, and diversion of management's attention from other business concerns

IT&E's future success depends in part upon its ability to recruit and retain key personnel.

IT&E's success to date has been, and its continuing success will be, substantially dependent on the continued services of its executive officers and other key personnel, who generally have experience in the industry. IT&E's success also depends, in large part, upon its ability to attract and retain highly qualified personnel familiar with current FDA regulations. IT&E may have difficulty locating and hiring qualified personnel to fill open positions, and retaining such personnel once hired. The loss of the services of any key employees, or IT&E's failure to attract and retain other qualified and experienced personnel on acceptable terms, could have an adverse effect on its business and results of operations.

Risks Related to IT&E's Industry

Competitors may harm IT&E's business by operating more effectively or more efficiently in its market.

Changes in the extensive regulations to which IT&E is subject could increase its cost of doing business or affect its ability to grow.

IT&E is subject to extensive federal regulation. New or revised interpretations of the regulations by any of the regulatory entities that determine IT&E's accreditation, could increase IT&E's cost of doing business.

Risks Related To Capital Structure

There is no assurance of an established public trading market.

Although the Registrant's common stock trades on the NASD OTC Bulletin Board, a regular trading market for the securities may not be sustained in the future. The NASD has enacted recent changes that limit quotations on the OTC Bulletin Board to securities of issuers that are current in their reports filed with the Securities and Exchange Commission. The effect on the OTC Bulletin Board of these rule changes and other proposed changes cannot be determined at this time. The OTC Bulletin Board is an inter-dealer, Over-The-Counter market that provides significantly less liquidity than the NASD's automated quotation system (the "NASDAQ Stock Market"). Quotes for stocks included on the OTC Bulletin Board are not listed in the financial sections of newspapers as are those for the NASDAQ Stock Market. Therefore, prices for securities traded solely on the OTC Bulletin Board may be difficult to obtain and holders of common stock may be unable to resell their securities at or near their original offering price or at any price. Market prices for the Registrant's common stock will be influenced by a number of factors, including:

- the issuance of new equity securities pursuant to this, or a future, offering;
- changes in interest rates;
- competitive developments, including announcements by competitors of new products or services or significant contracts, acquisitions, strategic partnerships, joint ventures or capital commitments;
- variations in quarterly operating results;
- change in financial estimates by securities analysts;
- the depth and liquidity of the market for Registrant's common stock;
- investor perceptions of our company and the technologies industries generally; and
- general economic and other national conditions.

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The Registrant's common stock could be considered a "penny stock."

The Registrant's common stock could be considered to be a "penny stock" if it meets one or more of the definitions in Rules 15g-2 through 15g-6 promulgated under Section 15(g) of the Securities Exchange Act of 1934, as amended. These include but are not limited to the following: (i) the stock trades at a price less than $5.00 per share; (ii) it is NOT traded on a "recognized" national exchange; (iii) it is NOT quoted on the NASDAQ Stock Market, or even if so, has a price less than $5.00 per share; or (iv) is issued by a company with net tangible assets less than $2.0 million, if in business more than a continuous three years, or with average revenues of less than $6.0 million for the past three years. The principal result or effect of being designated a "penny stock" is that securities broker-dealers cannot recommend the stock but must trade in it on an unsolicited basis.

Broker-dealer requirements may affect trading and liquidity.

Section 15(g) of the Securities Exchange Act of 1934, as amended, and Rule 15g-2 promulgated thereunder by the SEC require broker-dealers dealing in penny stocks to provide potential investors with a document disclosing the risks of penny stocks and to obtain a manually signed and dated written receipt of the document before effecting any transaction in a penny stock for the investor's account.

Potential investors in the Registrant's common stock are urged to obtain and read such disclosure carefully before purchasing any shares that are deemed to be "penny stock." Moreover, Rule 15g-9 requires broker-dealers in penny stocks to approve the account of any investor for transactions in such stocks before selling any penny stock to that investor. This procedure requires the broker-dealer to (i) obtain from the investor information concerning his or her financial situation, investment experience and investment objectives; (ii) reasonably determine, based on that information, that transactions in penny stocks are suitable for the investor and that the investor has sufficient knowledge and experience as to be reasonably capable of evaluating the risks of penny stock transactions; (iii) provide the investor with a written statement setting forth the basis on which the broker-dealer made the determination in (ii) above; and (iv) receive a signed and dated copy of such statement from the investor, confirming that it accurately reflects the investor's financial situation, investment experience and investment objectives. Compliance with these requirements may make it more difficult for holders of the Registrant's common stock to resell their shares to third parties or to otherwise dispose of them in the market or otherwise.

Special note regarding forward-looking statements

Some of the statements under "Risk Factors" and elsewhere in this Current

Report on Form 8-K constitute forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by such forward-looking statements.

In some cases, you can identify forward-looking statements by terminology such as "may," "will," "should," "could," "expects," "plans," "intends," "believes," "anticipates," "estimates," "predicts," "potential" or "continue" or the negative of such terms or other comparable terminology.

Although the Registrant believes that the expectations reflected in the forward-looking statements are reasonable, it cannot guarantee future results, levels of activity, performance, or achievements. Moreover, neither the Registrant nor any other person assumes responsibility for the accuracy and completeness of such statements. The Registrant is under no duty to update any
of the forward-looking statements after the date of this report.

Management Of The Registrant After The Effective Date Of The Acquisition

Directors And Executive Officers

In connection with the Reverse Acquisition, all of the Directors and Executive Officers of IT&E became directors and executive officers of the Registrant and Kamill Rohny resigned as the President, and Mr. Rohny and Dr. Boling resigned as directors of the Registrant. The following table sets forth the name and position of each of the Registrant's directors and executive officers immediately after the Effective Date of the Reverse Acquisition (April 14, 2004).

Name	Age	Position
Peter R. Sollenne	55	CEO/Director
Kelly Alberts	36	President/COO/Director
Tony Allocca	60	VP Ops/Director
Mike Ruchman	54	Vice President Sales

Biographies

Mr. Sollenne has served as our Chief Executive Officer since December 2003. From May 2000 to December 2003, Mr. Sollenne was President and Chief Executive Officer at FastBreak Growth, Inc. a strategic management consulting and business solutions company. From December 1998 to May 2000, Mr. Sollenne was Chief Executive Officer, President and Chief Operating Officer of re-Solutions, Inc., an information technology professional services company. Mr. Sollenne received his Bachelors of Science in Accounting/Business Administration from Boston College and is a CPA.

Kelly Alberts, Co-Founder, President/COO/Director

Mr Alberts has served as our President and Chief Operating Officer since our

inception in 1996. Mr. Alberts received his Bachelors of Science from the University of Iowa.

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Tony Allocca, Co-Founder, Vice President Operations/Director

Mr. Allocca has served as our Vice President of Operations since our inception in 1996. Mr. Allocca is a graduate of the University of Maryland and served in the United States Air Force.

Mike Ruchman, Vice President Sales

Mr. Ruchman has served as our Vice President of Sales since June, 2004. From 1999 to June 2004, Mr. Ruchman served as our Sales Director for Regulatory Compliance and Clinical consulting. From 1997 to 1999, Mike was the Vice President of Sales for XXCAL/NTS Corp. Mr. Ruchman holds a Bachelors of Science in Mechanical Engineering from California State University Los Angeles, a Masters of Science in Civil Engineering from California State University Los Angeles, a MBA and an MS in Information Systems Technology from the University of Texas.

Effective April 14, 2004, Kamill Rohny and Dr. Eugene Boling who were the Registrant's directors prior to the Effective Time of the Merger, resigned, in seriatim, and appointed its current directors and executive officers. See "Change in Control of Registrant" of Item 1, above, and "Management of the Registrant After the Effective Date of the Acquisition" of Item 2, above.

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ITEM 5.01. CHANGE IN CONTROL OF REGISTRANT.

On April 14, 2004, Clinical Trials Assistance Corporation, a Nevada corporation (the "Registrant") or ("CTAL"), Clinical Trials Assistance Acquisition Corporation, a Nevada corporation ("Merger Sub") and IT&E International, a privately-held California corporation ("IT&E"), entered into a Acquisition Agreement and Plan of Merger (collectively the "Agreement") pursuant to which the Registrant, through its wholly-owned subsidiary, Merger Sub, acquired IT&E in exchange for 11,000,000 shares of the Registrant's common stock which were issued to the holders of IT&E stock and 2,820,000 preferred shares, which can be converted for common shares at a ten-for-one ratio, after they are held for two years (the "Merger"). Immediately after the Acquisition was consummated and further to the Agreement, Kamill Rohny, the controlling stockholder of the Registrant, cancelled 28,000,000 shares of the Registrant's Common Stock held by him (the "Cancellation"). The transaction contemplated by the Agreement was intended to be a "tax-free" reorganization pursuant to the provisions of Section 351 and 368(a)(1)(A) of the Internal Revenue Code of 1986, as amended.

The stockholders of IT&E (three stockholders owning 481,500 shares), who unanimously approved the acquisition, and as of the closing date of the Merger and after giving effect to the Cancellation, now own approximately 80% of the Registrant's common stock outstanding as of June 10, 2004. This figure is based on the issuance of 11,000,000 common shares and the conversion of

the newly issued 2,820,000 Preferred Shares and the conversion of 2,000,000 outstanding warrants.

Under Nevada law, the Registrant did not need the approval of its stockholders to consummate the Acquisition and Merger, as the constituent corporations in the Merger were Merger Sub and IT&E, which are business entities incorporated under the laws of Nevada and California, respectively, and are in the same general business. The Registrant is not a constituent corporation in the Merger.

For accounting purposes, this transaction was being accounted for as a reverse merger, since the stockholders of IT&E own a majority of the issued and outstanding shares of common stock of the Registrant, and the directors and executive officers of IT&E became the directors and executive officers of the Registrant. Upon consummation of the Reverse Acquisition and after giving effect to the Cancellation, the members of the Board of Directors of the Registrant consisted of Peter R. Sollenne, Kelly Alberts and Tony Allocca; Mr. Rohny resigned as the President and Mr. Rohny and Dr. Boling resigned as Directors of the Company. No agreements exist among present or former controlling stockholders of the Registrant or present or former members of IT&E with respect to the election of the members of our board of directors, and to the Registrant's knowledge, no other agreements exist which might result in a change of control of the Registrant.

The Registrant intends to file an Information Statement on Schedule 14F1 with the U.S. Securities and Exchange Commission with respect to a change of directors for the Registrant.

Beneficial Owners

The following table shows the stockholdings of all directors and executive officers of the Registrant, principal stockholders who own beneficially more than five percent of the Registrant's issued and outstanding common stock, and all directors and officers of the Registrant as a group as of June 10, 2004, after giving effect to the Reverse Acquisition and the Cancellation, based on 19,000,000 shares outstanding at June 10, 2004.

Title of Class	Name and Address of Beneficial Owner of Shares	Position	Amount of shares held by Owner	Percent of Class (1)
Common	Kelly Alberts(2)	Pres/COO/Dir.	5,967,500	31.41%
Common	Tony Allocca(3)	VP Ops/Dir.	4,647,500	24.46%
Common	Peter R. Sollenne(4)	CEO/Director	385,000	2.03%
Common	Mike Ruchman (5)	VP Sales	-	-

Common	Kamill Rohny(6)	Shareholder	2,000,000	10.53%
All Executive Officers as a Group (4 persons)			11,000,000	57.89%

(1) The percentages listed in the Percent of Class column are based upon 19,000,000 issued and outstanding shares of Common Stock.

(2) Kelly Alberts, 31 N. Second Street, Suite 250, San Jose, CA 95113, he will also receive 1,529,850 Preferred shares which converts to ten-for-one common stock after a holding period of two years. These shares have ten-for-one voting rights.

(3) Tony Allocca, 31 N. Second Street, Suite 250, San Jose, CA 95113. he will also receive 1,191,450 Preferred shares which converts to ten-for-one common stock after a holding period of two years. These shares have ten-for-one voting rights.

(4) Peter R. Sollenne, 31 N. Second Street, Suite 250, San Jose, CA 95113. he will also receive 98,700 Preferred shares which converts to ten-for-one common stock after a holding period of two years. These shares have ten-for-one voting rights.

(5) Mike Ruchman, 31 N. Second Street, Suite 250, San Jose, CA 95113.

(6) Kamill Rohny, 2078 Redwood Crest, Vista, California 92081-7340.

ITEM 8.01. OTHER EVENTS

Based on the acquisition of IT&E International, the Registrant has moved its headquarters from 2078 Redwood Crest, Vista, California 92081-7340 to 31 N. Second Street, Suite 250, San Jose, CA 95113, Phone: 408-938-1000, effective April 14, 2004.

ITEM 9.01. FINANCIAL STATEMENTS, PRO FORMA FINANCIAL INFORMATION AND Exhibits.

(a) Financial Statements of business acquired.

The required financial statements of IT&E Corporation for the periods specified in Rule 3-05(b) of Regulation S-X are included herein. This Amended Current Report on Form 8-K amends Item 7(a) of the Form 8-K filed on April 15, 2004, by attaching hereto as Exhibit 99.2 and incorporating herein by reference the audited consolidated financial statements of IT&E Corporation for the years ended December 31, 2003 and 2002.

(b) Pro Forma Financial Information.

The required Pro Forma financial statements of IT&E Corporation for are included herein. This Amended Current Report on Form 8-K amends Item 7(b) of the Form 8-K filed on April 15, 2004, by attaching hereto as exhibit 99.3 and incorporating herein by reference the unaudited pro forma consolidated financial information of the Company and IT&E Corporation.

(c) Exhibits:

2.2	Revised Acquisition Agreement and Plan of Merger, dated as of April 14, 2004, by and among Clinical Trials Assistance Corporation, Clinical Trials Assistance Acquisition Corporation and IT&E Corporation, filed as Exhibit 2.2 to the Company's Form 8K filed with the Commission on April 14, 2004.
3.4	Amended Articles of Incorporation, date June 14, 2004, filed as Exhibit 3.4 to the Company's Amended Form 8K filed with the Commission on June 15, 2004.
99.2*	Audited Financials for IT&E Corporation
99.3*	Unaudited Pro Forma Consolidated Financial Information of the Company and IT&E Corporation

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*This filing.

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 hereunto duly authorized.

IT&E International Group

By: /s/ Peter Sollenne

Name: Peter Sollenne
Title: President

Dated: May 4, 2005

Exhibit Index

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