ERESEARCHTECHNOLOGY INC /DE/
Form 10-K
March 11, 2005

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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year ended December 31, 2004
or

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File No. 0-29100

eResearchTechnology, Inc.

(Exact name of issuer as specified in its charter)

Delaware	22-3264604
(State of incorporation)	(I.R.S. Employer Identification No.)

30 South 17th Street Philadelphia, PA 19103
(Address of Principal Executive Offices)

Registrant's telephone number, including area code: (215) 972-0420

Securities registered pursuant to Section 12(b) of the Act: None
Securities registered pursuant to Section 12(g) of the Act:
Common Stock, $.01 par value

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is an accelerated filer (as defined in Rule 12b-2 of the Act).Yes No

The aggregate market value of the registrant's Common Stock, $.01 par value, held by non-affiliates, computed by reference to the closing price of the Common Stock as reported by Nasdaq on June 30, 2004 was $1,329,782,972.

Number of shares of Common Stock of the registrant issued and outstanding as of March 3, 2005 was 50,399,265

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III (items 10, 11, 12, 13 and 14) is incorporated by reference from the Registrant's definitive proxy statement for its 2005 Annual Meeting of Stockholders, to be filed with the Commission pursuant to Regulation 14A.

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PART I

ITEM 1. BUSINESS
General

We were founded in 1977 to provide Cardiac Safety services to evaluate the safety of new drugs. We provide technology and services that enable the pharmaceutical, biotechnology and medical device industries to collect, interpret and distribute cardiac safety and clinical data more efficiently. We are a market leader in providing centralized electrocardiographic services (Cardiac Safety services or EXPeRT® ECG services) and a leading provider of technology and services that streamline the clinical trials process by enabling our clients to evolve from traditional, paper-based methods to electronic processing using our Clinical Data Management products and services.

Our solutions improve the accuracy, timeliness and efficiency of trial set-up, data collection from sites worldwide and interpretation and new drug, biologic and device application submission. We offer Cardiac Safety services, which are utilized by clinical trial sponsors and Clinical Research Organizations (CROs) during the conduct of clinical trials, including comprehensive Thorough QTc studies. Thorough QTc studies are typically of large volume and of short duration, with ECGs performed over a two to six month period. Services may be provided through the Digital ECG Franchise program, which offers a unique approach designed to address the growing capacity demands for eRT's ECG services through partnerships with sponsors that desire dedicated resources within eRT to address specific levels of cardiac safety monitoring transactions. We also offer site support which includes the rental and sale of cardiac safety equipment along with related supplies and freight. Additionally, we offer the licensing and, at the client's option, hosting of our proprietary Clinical Data Management software products and the provision of maintenance and consulting services in support of our proprietary Clinical Data Management software products.

We conduct our operations through offices in the United States and the United Kingdom (UK). Our international net revenues represented approximately 24%, 22% and 14% of total net revenues for the years ended December 31, 2002, 2003 and 2004, respectively. Revenues are recognized where the work is performed and not based upon the location of the client or the study. See Note 12 to the Consolidated Financial Statements appearing herein for information pertaining to our international operations.

Product and Service Offerings

Product/Services	**Description**
EXPeRT®	Diagnostic tests are employed in clinical trials to measure the effect of the product on certain body organs and systems in order to determine the product's safety. Cardiac Safety testing is one example of these diagnostic tests. Cardiac Safety services are provided by us through our regulatory compliant (Title 21 CFR, Part 11) EXPeRT® Cardiac Safety Intelligent Data Management System. EXPeRT® provides for workflow enabled cardiac safety data collection, interpretation and distribution of electrocardiographic (ECG) data and images as well as for analysis and cardiologist interpretation of ECGs performed on research subjects in connection with our clients' clinical trials. The ECG provides an electronic map of the heart's rhythm and structure, and typically is performed in most clinical trials. This service permits assessment of the safety of therapies by documenting the occurrence of cardiac electrical change. EXPeRT® is designed specifically to address the emerging global regulatory guidance and technical standards for digital ECG processing to include digital collection, waveform measurements and annotations, review and output to the regulatory standard file format. EXPeRT® also provides for paper-based ECG processing as well as for paper ECGs to be scanned into a digital format and then to be annotated and submitted to the cardiologist for interpretation. EXPeRT® includes the ability for ECGs to be

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viewed as side-by-side ECG images for comparison, supplemented by the ability to review prior patient ECG tracings. The Cardiac Safety data can be effectively distributed through the Digital ECG Community technology, which provides timely access to safety and related trial information in an easy to use format.

EXPeRT® further enhances our ECG services by permitting cardiologists, with training in our ECG interpretation guidelines and proper security access, to perform telecardiology, which is the ability to access and evaluate ECGs electronically in remote locations. We also establish rules for standardized, semi-automated and automated workflow management, allowing audit trail accounting and generating safety and operational metrics reports for sponsors and investigators.

These services, which we provide on a centralized basis, are required as part of many new drug studies. Continuous digital 12-lead ECG recordings or analog Holter recordings are also delivered to us for processing, interpretation and distribution of cardiac safety data. We also provide cardiac safety equipment to clients to perform the ECG and Holter recordings and provide electronic ECG collection and web-based data reporting services. Equipment rentals and sales, along with related supplies and freight, are included in our site support revenues.

We provide the following centralized ECG testing services as part of our EXPeRT® Cardiac Safety services:

- Digital ECG Services. Digital ECG Services allow the investigator to transmit, via modem, 12-lead ECG data directly to us for interpretation and rapid return of results to the investigator and the sponsor. ECGs are measured by our cardiac safety specialists utilizing an on screen, high-resolution caliper placement system, and are then interpreted by a cardiologist. We also offer cardiac safety specialist and cardiologist adjudication of software algorithm placed measurements where appropriate and as desired by our clients.

- Continuous Digital 12-lead ECG Recording. Continuous digital 12-lead ECG signals are recorded for up to 24 hours onto compact flash memory cards and submitted to us. From these recordings, 12-lead ECGs can be evaluated at specific time points. These ECGs are measured by a cardiac safety specialist and then interpreted by a cardiologist. Continuous digital 12-lead ECG recordings can also be used for studies assessing the incidence of arrhythmias, cardiac ischemia and/or heart rate variability findings.

- Holter Recording. Holter recording is a 24- or 48-hour continuous ECG recording of the heart s rhythm on a cassette tape that is reviewed by a cardiac safety specialist and then by a cardiologist. Holter data reported by us is provided for studies assessing the incidence of arrhythmias, cardiac ischemia and/or heart rate variability.

- Paper ECG Services. Paper ECGs are measured by our cardiac safety specialists utilizing a high-resolution digitizing system, and are then interpreted by a cardiologist. Alternatively, paper ECGs may be scanned to a digital format, where appropriate.

- FDA XML ECG Service. FDA XML (Extensible Markup Language) ECG service provides our clients with electronic versions of each ECG processed by EXPeRT®. The ECGs processed by EXPeRT® are

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	rendered in a format compliant with the FDA's emerging XML standard for digital ECGs.
	▪ The Digital ECG Community, a hosted solution based on the eResearch Community® application, delivers near real time Cardiac Safety feedback at the program, trial, center and patient level, along with related metrics, such as trial enrollment, as well as the ability to organize and publish a variety of study-specific information and the ability to link data points in reports direct to digital ECG waveforms.
eResearch Community® (eRC®)	A central command and control portal that provides real-time information related to monitoring clinical (eRC®) trial activities, data quality and safety. The eRC technology is specifically designed to optimize clinical research assets – people, processes and information – by providing the participants in clinical research access to real time analysis and decision support capabilities along with a wide array of value added services and content designed to optimize the clinical research process. eRC includes our eResearch Dashboard® module, which allows participants in the clinical trial to follow the progress and conduct of a study based on frequently updated data. This product allows the participant to analyze data and generate reports in a broad variety of formats that permit early strategic intervention in the clinical trial. eRC also includes a web-based training environment, eHealth Education®, that allows clinical research professionals to learn about technology developments, new products, clinical protocols, and other educational matters.
eData Entry® (eDE®)	A comprehensive electronic data capture (EDC) system comprised of technology and consulting services formulated to deliver rapid time to benefit for electronic trial initiatives. Among the EDC offerings is a hosted turnkey electronic clinical trial environment that requires no capital investment or significant business process redesign. The program includes comprehensive system implementation, study support, and site support services. Sponsor, CRO and investigative site access is delivered through our eRC, a clinical research portal that serves as a focal point for trial stakeholders accessing our EDC technology, eResearch Dashboard® key trial metrics, and related trial information.
eResearch Network® (eResNet®)	An integrated end-to-end clinical research solution that allows a sponsor or CRO to establish an infrastructure that connects multiple participants in the clinical trial process and that can be used repeatedly for future clinical trials. As an established infrastructure, an eResNet will allow a sponsor or CRO to improve the efficiency and speed of the clinical trial by automating the process for conducting each new clinical trial. The eResNet includes the following modules:
eData Management® (eDM®)	A clinical data management application for collecting, cleaning and managing clinical trial data. Clients use this technology to analyze data, resolve incomplete or erroneous data entries and support early locking of the database for a particular trial. This product easily integrates with a wide variety of third-party software applications in areas such as data analysis.
eSafety Net®	An adverse event management system. This application facilitates compliance by sponsors, CROs and investigators with regulatory reporting requirements regarding adverse events and with the sponsor's or CRO's own internal requirements for safety data analysis.

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eStudy Conduct	A clinical trial management technology that can be used to set up clinical trials, establish standards, track study activities, plan resources, distribute supplies, manage the financial aspects of a trial and electronically view clinical trial data.
Project Assurance/ Implementation Assurance	We provide a full spectrum of consulting services for all of our products that augment the study management and implementation efforts of clients in support of their clinical research requirements. The methodologies (Project Assurance for Cardiac Safety and Implementation Assurance for Clinical Data Applications) provide a consistent framework through which we can effectively manage the delivery of all products and services. Such methodologies provide the standards, guidelines and services that allow us to effectively anticipate our clients needs and assure proactive communication and implementation in order to meet and exceed our clients goals. The services include study initiation, project management, education, site qualification, configuration, technology and regulatory review, research dashboards and electronic reporting, data management, uniform standards and standard operating procedures, and migration services. In addition, we provide on-site research and technology advisory services, support services including online and help desk support and software maintenance.

All of our technology offerings, which include the eResearch Community, eData Entry and eResearch Network, are available to be licensed over a renewable annual term (annual license) in addition to a traditional perpetual license with annual maintenance. All technology offerings may, at our client s option, be hosted by a third party we designate or installed on our client s computing infrastructure. Through our flexible offerings, we seek to build market share and obtain clients who were not otherwise willing to purchase software solutions by traditional means. Also, the eRC annual license is positioned for organizations that have implemented systems from multiple vendors in areas as diverse as EDC, laboratory information management, trial management, clinical data management and adverse event management. This technology enables clients to address a long standing problem with regard to the inability to aggregate, integrate and provide access to disparate clinical data from a variety of sources that is required to make timely decisions.

Our products use common interfaces and common data delivery standards, allowing clinical trial participants to learn how to use additional applications with minimal training. By establishing common naming standards for data that clinical trial participants may share across applications, departments and global locations, sponsors and CROs can improve data integrity and accelerate reconciliation of information. Our products and services can work with and connect to leading third party finance, enterprise resource planning, and research software through a batch load utility that we have developed.

Technology

Our eResNet, eDE, eRC and EXPeRT® applications were developed with web architectures. We developed these applications using industry-standard development tools including XML, HTML, Java and Oracle Developer, all of which provide rapid access to the underlying Oracle database. Our philosophy of using industry-standard tools allows us to focus our attention on the features and functions delivered through the client interface and the application layer in order to meet our clients strategic business requirements. Our clients also use those tools to benefit from the underlying data stored in the clinical database.

Our eDE product was enhanced in 2003 to eliminate the requirement for users to install any software locally on their desktops. This zero-footprint design enhancement simplifies the validation process for our clients, thus enabling faster adoption of our EDC product and services.

The capacity of our EXPeRT® processing platforms was significantly expanded in 2003 by optimizing our software application and increasing the number of servers and their processing speeds. These enhancements to our capacity continue to provide us the capability for handling the continued and significant growth in the volume of ECGs being processed. In addition, a number of new reports for sponsors and internal use were added to

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EXPeRT® during 2003 and 2004. EXPeRT® was functionally enhanced in 2004 to provide additional workflow scenarios for semi-automated processing of ECGs, whereby cardiac safety specialists and cardiologists are presented with software derived ECG measurements for the cardiac safety specialists and cardiologists to confirm or adjudicate.

Research and Development

We have been developing our products and services for more than 20 years through our current business or through that of our predecessors. Our applications have progressed from mainframe through two-tiered client-server processing and are now three-tiered web architecture. We have developed our software to take advantage of the power of the Internet. We continue to advance our products by enhancing the human interface of the modules.

As of December 31, 2004, we had 37 employees engaged in research and development, together with 8 consultants. Our research and development efforts are focused on improving and enhancing our existing products and services as well as developing new products and services. We have also partnered with other companies to broaden our product offerings.

We developed an internal application service provider capability in support of our Digital ECG Community service offering. Additionally, we have a relationship with International Business Machines Corporation (IBM) to deliver the eResNet, EDC and eRC as a hosted offering. Research and development expenses were $4.3 million for 2002, $4.6 million for 2003 and $4.1 million for 2004.

Our Clients

We serve pharmaceutical, biotechnology and medical device companies as well as CROs. We have master service agreements with 137 clients, which establish the overall contractual relationship between us and our clients, and Digital ECG Franchise agreements with 3 clients. We provide our solutions to 28 of the 50 largest pharmaceutical companies globally. In 2004, Novartis AG, at 17%, was the only client that accounted for 10% or more of our consolidated net revenues.

Sales and Marketing

We market and sell products and services primarily through our global direct sales, sales support, and professional services organization. As of December 31, 2004, our Business Development Team consisted of 44 sales, marketing and consulting professionals worldwide, which included a direct sales force of 23 sales professionals located in Philadelphia, Pennsylvania, Bridgewater, New Jersey and Peterborough, United Kingdom.

We focus our marketing efforts on educating our target market, generating new sales opportunities and increasing awareness of our solutions. We conduct a variety of marketing programs globally, including vendor days at clients offices, business seminars, trade shows, public relations, industry analyst programs, and advisory councils.

Our sales cycle generally begins with our response to a request from a sponsor or CRO for a proposal to address a client-specific research requirement. We then engage at our expense in a series of consultations, workshops, implementation reviews, final proposals and contract negotiations prior to the time when the prospective client has any obligation to purchase our products or services. During this process, we involve our sales, consulting and senior management personnel in a collaborative approach. Our sales cycle can vary from a few weeks to as long as nine months depending upon the scope of the products and services being discussed and the scope of the clinical trial.

Partnerships

Recent regulatory guidance recommends thorough cardiac safety monitoring in specially designed Phase I trials. We expect work in this Thorough QTc Study area will be performed by organizations valued for their capability, capacity, science, process and compliance. We have formalized agreements with Clinical Pharmacology Units

(CPUs) that understand the need to provide cardiac safety assessments to their clients

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consistent with the recent guidance. CPUs provide a range of services including the conduct of clinical studies to comprehensively explore safety, tolerability, pharmacokinetics and pharmacodynamics of novel compounds. We have developed relationships with various CPUs in which we provided our Cardiac Safety services to the clients of these CPUs. Our alliances enable us and the CPUs to deliver fully integrated Clinical Pharmacology solutions to drug developers. We also have working relationships with other CPUs that are not part of a formal eRT Clinical Pharmacology partnership.

Competition

The market for our products and services is extremely fragmented, with hundreds of companies providing niche solutions to satisfy small parts of the clinical research process. We believe we are the only provider of technology-based solutions in the clinical research industry that offers end-to-end research solutions that enable electronic processing while also addressing manual, paper-based processes used in clinical research. We were the first company to utilize specifically developed technology to address the digital regulatory initiative in providing ECG services.

The market for our solutions is intensely competitive, continuously evolving and subject to rapid technological change. The intensity of competition has increased and is expected to further increase in the future. This increased competition could result in price reductions, reduced gross margins and loss of market share, any one of which could seriously harm our business. Competitors vary in size and in the scope and breadth of the products and services offered.

We believe that the principal competitive factors affecting our market include:

- client service
- a significant base of reference clients
- breadth and depth of solution, including the ability to accommodate both electronic forms and manual, paper-based research methods of data collection, management and analysis
- product quality and performance
- core technology and product features
- ability to implement solutions
- capacity
- price
- financial and organizational stability
- ability to adapt to changing regulatory guidance

We believe that our solutions currently compete favorably with respect to these factors, and we will continue to strive to maintain our competitive edge in the marketplace.

Government Regulation

Human pharmaceutical products, biological products and blood derivatives and medical devices are subject to rigorous government regulation. In the United States, the principal federal regulatory agency is the Food and Drug Administration (FDA) and there are some similar state agencies. Foreign governments also regulate these products when they are tested or marketed abroad. In the United States, the FDA has established standards for conducting clinical trials leading to the approval for new products.

Because our products and services assist the sponsor or CRO in conducting the trial and preparing the new drug, biologic or device application, we must comply with these requirements. We also must comply with similar

regulatory requirements in foreign countries. These foreign regulations vary somewhat from country to country, but generally establish requirements similar to those of the FDA.

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In March 1997, the FDA promulgated regulations related to requirements for computer systems that support electronic records and electronic signatures. These regulations define requirements for system control, security, authentication, validation and retention of electronic records. The FDA issued a guidance document Part 11 Electronic Records; Electronic Signatures Scope and Applicability (August 2003) which defines the FDA s current thinking on the implementation of the 1997 regulation 21 CFR Part 11 and also noted there would be enforcement discretion of specific requirements.

The Health Insurance Portability and Accountability Act of 1996 established certain requirements relating to the privacy and security of personal health information. The act directly covers how health plans, health care clearinghouses and most health care providers transmit, store, use and disclose individually identifiable health information. Covered uses and disclosures include uses and disclosures for purposes of clinical trials or other activities regulated by the FDA.

In November 2001, the FDA held a public meeting at which it proposed requiring sponsors of new drugs to submit ECG raw data in digital format and annotated digital ECG waveforms. Annotated waveforms include definition of measurement points that are used to create ECG analysis data. A more recent meeting held in January 2003, which was supported by a preliminary concept paper issued in November 2002, further discussed the trial design, ECG acquisition, analysis and reporting for digital ECGs. Following a meeting in June 2004, the International Conference on Harmonization (ICH) released to the public in September 2004 the following guidelines at Step 3, S7B: Safety Pharmacology Studies for Assessing the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals and E14: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs. The objective of these guidelines is to recommend the design and timing of studies in the clinical development process and provide general recommendations on available non-clinical methodologies to assess the potential risk of QT interval prolongation of a pharmaceutical product. At Step 3, the guideline is under regulatory consideration by the three regions (US, EU and Japan). The FDA and ICH are scheduled to meet in April 2005 and May 2005, respectively. We believe that, as a result of these meetings, the regulators will reinforce the importance of cardiac safety testing in clinical trials and will further clarify the regulatory guidance last provided in September 2004. There is currently no defined timeline for completion of Step 4 (adoption of a tripartite harmonized text) and Step 5 (implementation by regulatory regions). The results of the non-clinical studies outlined in these guidelines contribute to the design and evaluation of clinical trials to determine the potential risk of QT prolongation in humans. As a result, the evaluation methodology and trial designs supported by eRT will be driven by the outcomes of these non-clinical studies.

We believe that we have designed our products and services to be consistent with the recommendations of the relevant regulatory bodies as referred to above and to comply with applicable regulatory requirements.

Potential Liability and Insurance

We attempt to manage our risk of liability for personal injury or death to study subjects from administration of products under study through contractual indemnification provisions with clients and through insurance maintained by our clients and us. Contractual indemnification generally does not protect us against certain of our own actions, such as negligence. The terms and scope of such indemnification vary from client to client and from trial to trial. Although most of our clients are large, well-capitalized companies, the financial viability of these indemnification provisions cannot be assured. Therefore, we bear the risk that the indemnifying party may not have the financial ability to fulfill its indemnification obligations to us. We maintain errors and omissions liability insurance in the amount of $6 million per claim and professional liability insurance in the amount of $1 million per claim. Our operating results could be materially and adversely affected if we were required to pay damages or incur defense costs in connection with a claim that is beyond the scope of an indemnity provision or beyond the scope or level of insurance coverage maintained by us or the client or where the indemnifying party does not fulfill its indemnification obligations to us.

Intellectual Property

Our services have been enhanced by significant investment in information technology. Our information services group is committed to achieving operating efficiencies through technical advances. We have developed certain computer software and technically derived procedures, as well as created internal operational processes, which we seek to protect through a combination of contract law, trademarks and trade secrets, including seeking

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registration of trademarks and patent protection in several jurisdictions. We believe that our technical capabilities and operational processes provide significant benefits to our clients.

On March 16, 2004, we were issued United States Patent No. 6,708,057 (the 057 Patent) for various methods and systems for processing electrocardiograms. The methods and systems have particular utility in the collection and interpretation of electrocardiograms developed during clinical trials. The 057 Patent includes more than 50 claims directed to various features of our EXPeRT® workflow enabled data handling technology.

eRT has also filed patent applications in Canada, India and the European Patent Office, all of which are pending. eRT has filed a continuation application in the United States Patent Office in late 2004 pursuing alternative claim coverage and expects to receive a substantive examination of the application in late 2005 or early 2006.

Employees

At December 31, 2004, we had a total of 353 employees, with 284 employees (275 full-time, 9 part-time) at our locations in the United States and 69 full-time employees at our location in the United Kingdom. We had 234 employees performing services directly for our clients, 37 employees in research and development, 44 employees in sales and marketing and 38 employees involved in general and administrative activities.

We are not a party to any collective bargaining agreements covering any of our employees, have never experienced any material labor disruption and are unaware of any current efforts or plans to unionize our employees. We consider our relationship with our employees to be good.

Website

Our website address is www.ert.com. We have posted to our website each annual report on Form 10-K, quarterly report on Form 10-Q, current report on Form 8-K, and all amendments to these reports and, since November 15, 2002, have posted such reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission. You may access and print these forms free of charge from our website.

ITEM 2. PROPERTIES

Our corporate headquarters are located at 30 South 17th Street, Philadelphia, Pennsylvania, where we lease approximately 39,000 square feet, of which approximately 840 square feet is subleased to a third party. Our lease expires in August 2008. We also lease approximately 31,000 square feet of office space in Bridgewater, New Jersey, which expires in January 2011. Additionally, we entered into a lease in September 2004 for approximately 18,000 square feet of office space in Peterborough, United Kingdom, which expires in June 2013. This office is a replacement for approximately 9,000 square feet of office space in Peterborough, the lease for which expires in March 2005.

We anticipate that we may require additional space for our operations as we expand, and believe that suitable additional or alternative space will be available in the future on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS

In April 2003, we were named as a defendant in an action brought in the Superior Court for Middlesex County, Commonwealth of Massachusetts (Barbara L. Budge et al. v. Robert Kleiman, M.D., et al. (Civ. Act. No. MICV 2003-01728)). The compliant alleges that our company and Dr. Kleiman, who performed services during the relevant period as an independent contractor for us, were negligent in treatment of one of the plaintiffs, resulting in various injuries for which plaintiffs seek unspecified damages. One of the plaintiffs was a subject in a clinical trial for which we were providing certain services to the trial s sponsor. Pursuant to the agreement under which the services were performed, our company and our agents are entitled to indemnification from the sponsor for claims such as those asserted by the plaintiffs. The sponsor has agreed to reimburse our company for the cost of our defense and to indemnify our company and Dr. Kleiman in this matter, subject to a reservation of rights in the event the facts establish that either our company or Dr. Kleiman is not entitled to indemnification in accordance with the terms of the agreement. Dr. Kleiman has been dismissed as a defendant and discovery has

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commenced and is expected to be completed in June 2005. We believe we have meritorious defenses and we intend to defend this matter vigorously.

In December 2003, we were named as a defendant in an action brought in Common Pleas Court for Philadelphia County, Commonwealth of Pennsylvania (Colburn et al. v. eResearchTechnology, Inc. (No. 002521 Dec. Term 2003)). The amended complaint is based on a warrant that entitled the plaintiffs alleged predecessor-in-interest to purchase $1.0 million worth of shares in our former wholly-owned subsidiary (the Former Subsidiary) if the Former Subsidiary completed an initial public offering of its common stock. The exercise price for the warrant was to be established upon the occurrence of the Former Subsidiarys initial public offering of its common stock. The initial public offering never took place. The plaintiffs allege that the subsequent merger of the Former Subsidiary with and into our company, as a result of which the separate legal existence of the Former Subsidiary ceased and our company was the surviving corporation, constituted a de facto initial public offering. The amended complaint alleges breach of contract, unjust enrichment and promissory estoppel. The plaintiffs also seek declaratory relief entitling them to exercise a warrant for 574,713 shares of our common stock at an exercise price of $1.74 per share. Formal discovery has commenced and is expected to be completed in March 2005. We believe we have meritorious defenses and intend to defend this matter vigorously.

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

We did not submit any matters during the fourth quarter of the year covered by this Form 10-K to a vote of the security holders through the solicitation of proxies or otherwise.

SPECIAL ITEM. EXECUTIVE OFFICERS OF REGISTRANT

Officers are elected by the Board of Directors and serve at the pleasure of the Board. Our executive officers are as follows:

Name	Age	Position
Joseph A. Esposito	52	President, Chief Executive Officer and Director
Joel Morganroth, MD	59	Chairman of the Board of Directors and Chief Scientist
Robert S. Brown	49	Senior Vice President, Outsourcing Partnerships
Thomas P. Devine	52	Senior Vice President and Chief Development Officer
Amy Furlong	32	Senior Vice President, Regulatory Compliance
Scott Grisanti	42	Senior Vice President, Business Development and Chief Marketing Officer
Bruce Johnson	54	Senior Vice President and Chief Financial Officer
Jeffrey S. Litwin, MD	47	Senior Vice President and Chief Medical Officer
Anna Marie Pagliaccetti, Esq.	39	Senior Vice President, General Counsel and Secretary
Vincent Renz	48	Senior Vice President, Client Services and Chief Technology Officer
George Tiger	45	Senior Vice President, International Operations

Mr. Esposito has served as our President and Chief Executive Officer since March 2001. Mr. Esposito formerly served as our President and Chief Operating Officer from April 1998 until March 2001 and has served as a member of our Board of Directors since 1999. He also served as President of our Clinical Research Technology and Services division from October 1997 to April 1998. From May 1997 through October 1997, he was President of DLB Systems, Inc. which we acquired in October 1997. He has over 28 years experience in technology, working closely with pharmaceutical companies in the areas of clinical research, supply chain management and regulatory document management. Mr. Esposito was awarded the 2002 Ellis Island Medal of Honor by Congress and the National Ethnic Coalition Organization for outstanding citizenship, individual achievement and encouragement of cultural unity.

Dr. Morganroth has served as our Chairman since 1999, our Chief Scientist since March 2001 and a member of our Board of Directors since 1997. He served as our Chief Executive Officer from 1993 to March 2001. In addition, Dr. Morganroth has consulted for us since 1977. Dr. Morganroth is a globally recognized cardiologist and clinical researcher. Dr. Morganroth served for over ten years as a Medical Review Officer/Expert for the U.S. Food and Drug Administration.

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Mr. Brown has been our Senior Vice President, Outsourcing Partnerships since July 2002. From January 2000 to June 2002, Mr. Brown was our Senior Vice President, Cardiac Safety. From December 1997 to December 1999, Mr. Brown served as our Vice President, Business Development. Mr. Brown has been employed with us for over 22 years.

Mr. Devine has been our Senior Vice President and Chief Development Officer since April 2003. From August 2002 to April 2003, Mr. Devine was our Vice President of Research and Development. Prior to joining us, Mr. Devine was employed by ecHUB, Inc., an electronic commerce company, from January 2000 to July 2002. Prior to that, Mr. Devine worked for Lockheed Martin for three years after spending approximately 16 years at IBM.

Ms. Furlong has been our Senior Vice President, Regulatory Compliance since January 2004. She previously served as our Vice President, Regulatory Compliance since February 2001 and Sr. Director, Regulatory Compliance since February 1999. Ms. Furlong has been employed with our company since December 1995.

Mr. Grisanti has been our Senior Vice President, Business Development and Chief Marketing Officer since October 2000. Mr. Grisanti was previously employed by ClearCross, Inc., a provider of global commerce management solutions, from November 1998 to October 2000, most recently as Area Vice President of Sales.

Mr. Johnson has been our Senior Vice President and Chief Financial Officer since February 2000. He also served as our Secretary from February 2000 to April 2002. Mr. Johnson has 30 years of previous experience in public accounting and financial management positions. Mr. Johnson is a certified public accountant.

Dr. Litwin is a cardiologist and has been our Senior Vice President and Chief Medical Officer since July 2000. Dr. Litwin was previously employed by Executive Health Group, a leading international provider of physical examinations for corporate executives, from May 1993 to July 2000, most recently as Executive Vice President and Chief Operating Officer. Dr. Litwin also served as a consultant for Schlumberger, Ltd. from March 1996 to July 2000.

Ms. Pagliaccetti has been our Senior Vice President and General Counsel since January 2004. She previously served as our Vice President and General Counsel since August 2001. She has also served as our Secretary since April 2002. From March 2000 to August 2001, Ms. Pagliaccetti served as our Corporate Controller and Associate General Counsel. Ms. Pagliaccetti is licensed to practice law in Pennsylvania and is also a certified public accountant.

Mr. Renz has been our Senior Vice President, Client Services and Chief Technology Officer since April 2004. Previously, Mr. Renz served as our Senior Vice President, Technology and Consulting and Chief Technology Officer from January 2000 to March 2004. Mr. Renz served as our Vice President and General Manager of our Clinical Research Technology and Services division from May 1998 to December 1999. Mr. Renz has over 20 years of experience in developing and implementing information technology products and services.

Mr. Tiger has been our Senior Vice President, International Operations since July 2004. Previously, Mr. Tiger served as Vice President, International Business Development from August 2002 to July 2004 and as Director of Business Development from January 2001 to August 2002. Prior to joining us, Mr. Tiger worked for Celsis International as Vice President of Sales and Marketing for its laboratory group for four years after spending nearly 10 years with Abbott Laboratories.

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PART II

ITEM 5. MARKET FOR REGISTRANT□S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Our common stock has been traded on the Nasdaq National Market System since February 4, 1997, currently under the symbol □ERES.□ Below is the range of high and low sales prices for the common stock for the following quarters as quoted on the Nasdaq National Market System. On May 29, 2003, we effected a 2-for-1 split of our common stock and on November 26, 2003 and May 27, 2004, we effected 3-for-2 splits of our common stock. Market prices in the following table have been restated to reflect these splits of our common stock as if the stock splits had occurred as of December 31, 2002.

Calendar Period	High	Low
2003		
First Quarter	$ 6.11	$ 3.50
Second Quarter	10.45	5.72
Third Quarter	17.58	9.17
Fourth Quarter	22.49	13.78
2004		
First Quarter	$ 24.93	$ 17.12
Second Quarter	28.08	18.47
Third Quarter	29.80	13.13
Fourth Quarter	16.86	10.70

We have never declared or paid any cash dividend on our common stock. We do not anticipate paying any cash dividends in the foreseeable future because we intend to retain our current cash and future earnings for the development and expansion of our business.

As of March 3, 2005, there were 52 record holders of our common stock.

We announced on April 21, 2004 that our Board of Directors authorized a common stock buyback program of up to 500,000 shares with no expiration date. We announced on October 21, 2004 that our Board of Directors authorized the purchase of up to an additional 2 million shares, to extend the buyback program to a total of 2.5 million shares. Through December 31, 2004, we repurchased 2.0 million shares of the 2.5 million shares approved for repurchase. The following table provides information regarding the stock buy-back activity during the fiscal quarter ended December 31, 2004:

ISSUER PURCHASES OF EQUITY SECURITIES

Period	(a) Total Number of Shares Purchased	(b) Average Price Paid per Share	(c) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
October 1 through October 31	575,000	$ 11.15	575,000	1,625,000
November 1 through November 30	930,000	$ 13.09	930,000	695,000
December 1 through December 31	200,000	$ 15.12	200,000	495,000
Total for the quarter	1,705,000			