

ERESEARCHTECHNOLOGY INC /DE/  
Form 10-K  
March 15, 2004

## 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, 2003

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  
(State of incorporation)

22-3264604  
(I.R.S. Employer Identification No.)  
30 South 17th Street Philadelphia, PA 19103  
(Address of Principal Executive Offices  Zip Code)

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, 2003 was \$430,389,598.

Number of shares of Common Stock of the registrant issued and outstanding  
as of March 11, 2004 was 34,137,930

**DOCUMENTS INCORPORATED BY REFERENCE**

The information required by Part III (items 10, 11, 12 and 13) is incorporated by reference from the Registrant's definitive proxy statement for its 2004 Annual Meeting of Stockholders, to be filed with the Commission pursuant to Regulation 14A.

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[Back to Contents](#)**PART I****ITEM 1. BUSINESS****General**

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 eECG 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.

We were founded in 1977 to provide Cardiac Safety services to evaluate the safety of new drugs. In February 1997, we completed an initial public offering of our common stock. In October 1997, we acquired the assets and business of a provider of clinical data management technology and consulting services to the pharmaceutical, biotechnology and medical device industries. In the second half of 1999, we closed our international Clinical Research Organization (CRO) operation, including clinical trial and data management services, and in December 1999 we sold our domestic CRO operation to SCP Communications, Inc.

Our solutions improve the accuracy, timeliness and efficiency of trial set-up, data collection and interpretation and new drug, biologic and device application submission. We offer Cardiac Safety services, which are utilized by clinical trial sponsors and CROs during their conduct of clinical trials, including comprehensive Thorough Phase I ECG studies. 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. 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 21%, 24% and 22% of total net revenues for the years ended December 31, 2001, 2002 and 2003, respectively. See Note 12 to the Consolidated Financial Statements appearing herein for information pertaining to our international operations.

**Product and Service Offerings**

<b>Product/Services</b>	<b>Description</b>
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 physician electrocardiographer 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.

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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 physician electrocardiographer for interpretation. EXPeRT includes the ability for ECGs to be 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 physician electrocardiographers, 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 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. Digital 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 ECGs and Holter recordings and provide electronic ECG collection and web-based data reporting services.

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 telephonically transmit 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 physician electrocardiographer. We also offer cardiologist adjudication of machine placed measures where appropriate and desired by our clients.

**Digital 12-lead Holter Recording.** Digital 12-lead Holter Recording is a continuous recording of 12-lead ECGs for up to 24-hours. Digital 12-lead ECG signals are recorded 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 physician electrocardiographer. Digital 12-lead Holter 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 physician electrocardiographer. Holter data reported by us is provided for studies assessing the incidence of arrhythmias, cardiac ischemia and/or heart rate variability findings.

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Paper ECG Services. Paper ECGs are measured by our cardiac safety specialists utilizing a high-resolution digitizing system, and are then interpreted by a physician electrocardiographer.

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 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 eResCom application, delivers 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 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:

eStudy Conduct[]

A clinical trial management technology 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.

eData Management (eDM[])

A clinical data management application for collecting, editing and managing clinical trial data in any computing environment. 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. Sponsors or CROs can utilize this application to match their own processes and forms.

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 eResearch Community[] (eResCom), 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.

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eResearch  
Community(eResCom)

A central command and control portal that provides real-time information related to monitoring clinical trial activities, data quality and safety. The eResCom 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. eResCom includes our eResearch Dashboard and eHealth Education modules, which allow 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. eResCom also includes a web-based training environment that allows clinical research professionals to learn about technology developments, new products, clinical protocols and other educational matters.

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 are available to be licensed over a renewable annual term (annual license) in addition to a traditional perpetual license with annual maintenance, with the exception of eDE, which is offered only through an annual license or a license corresponding to the length of a specific trial. 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 eResCom 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, eResCom 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-



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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 electronic data capture product and services.

The capacity of our EXPeRT processing platforms was significantly expanded in 2003 by optimizing our software application and increasing the number and processing speeds of our server infrastructure. 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.

### **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, 2003, we had 30 employees engaged in research and development, together with 11 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 are also partnering 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 eResCom as a hosted offering. Research and development expenses were \$4.9 million for 2001, \$4.3 million for 2002 and \$4.6 million for 2003.

### **Our Clients**

We serve pharmaceutical, biotechnology and medical device companies as well as CROs. We have master service agreements, which establish the overall contractual relationship between us and our clients, with 100 clients and Digital ECG Franchise agreements with three clients. We provide our solutions to 28 of the 50 largest pharmaceutical companies globally, as well as 54 clients with software modules installed worldwide. In 2003, one client, Novartis AG, 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, 2003, our Business Development Team consisted of approximately 40 sales, marketing and consulting professionals worldwide, which included a direct sales force of 22 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 an annual software users conference, vendor days at clients' offices, business seminars, trade shows, press relations and 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

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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 requires [thorough] cardiac safety monitoring in specially designed Phase I trials. Increasingly, we expect work in this Thorough Phase I ECG 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 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.

A formal partnership with Siemens Medical Solutions was signed in 2003 to embed our entire electronic clinical trial processing technology offering into Siemens' information technology and operations platform enabling Siemens to expand into the market of clinical data management. The alliance will provide Siemens and its clients with integrated access to our solutions to create an application infrastructure to support EDC trials targeted for the life sciences and health care markets. We will provide technology transfer services to include a wide range of regulatory compliant hosting, application configuration, regulatory validation, knowledge transfer consulting, Web-based training curricula, software maintenance and support and EDC site support.

### **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. With the launch of EXPeRT in August 2002, we were the first company to utilize technology to address the digital regulatory initiative in providing ECG services.

The market for our solution 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



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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 and animal 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, biologics, 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.

In March 1997, the FDA promulgated regulations related to requirements for computer systems which support electronic records and electronic signatures. These regulations define requirements for system control, security, authentication, validation and retention of electronic records. The FDA has issued several guideline documents associated with the use of computerized systems in clinical trials and management of electronic records. The guidelines outline the controls for those who use computerized systems in clinical trials to ensure the same degree of integrity as exists with paper-based systems.

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. Annotated data refers to the defining of measurement points and events that are used in the analysis of such 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. In February 2002, the International Conference on Harmonization (ICH) released (at Step 3) S7B: Safety Pharmacology Studies for Assessing the Potential for Delayed Ventricular Repolarization (QT Interval Prolongation) by Human Pharmaceuticals. The objective of this guideline 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 next ICH meeting is scheduled for June 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 FDA's recommendations 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 patients 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

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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 that we seek to protect through a combination of contract law, trademarks and trade secrets. We have sought patent protection in the United States, Canada and the European Union for certain aspects of our method and systems for processing ECGs through the EXPeRT system, although there is no assurance such protection will be granted. Although we do not believe that our intellectual property rights are as important to our results of operations as are such factors as technical expertise, knowledge, ability and experience of our professionals, we believe that our technical capabilities provide significant benefits to our clients.

### **Employees**

At December 31, 2003, we had a total of 284 employees, with 227 employees (223 full-time, 4 part-time) at our locations in the United States and 57 full-time employees at our location in the United Kingdom. We had 183 employees performing services directly for our clients, 30 employees in research and development, 40 employees in sales and marketing and 31 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](http://www.ert.com). We have posted to our website each annual report on Form 10-K, quarterly report on Form 10-Q, current reports 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. We also lease approximately 9,000 square feet of office space in Peterborough, United Kingdom, which expires in September 2009.

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 complaint 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

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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 plaintiff. 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 commenced. 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 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") at an exercise price to be established upon the occurrence of the Former Subsidiary's 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 complaint alleges breach of contract, unjust enrichment and promissory estoppel. The plaintiffs also seek declaratory relief entitling them to exercise a warrant for 383,142 shares of our common stock at an exercise price of \$2.61 per share. Although the case is in the early stages of litigation and formal discovery has not commenced, we believe we have meritorious defenses and intend to defend this matter vigorously.

Although we have reported these matters in this Form 10-K for the information of our stockholders, we do not believe these matters are material to our company and, pending any material development, we do not intend to disclose these matters in future Reports on Form 10-K or 10-Q.

#### **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 Report 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:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Joseph A. Esposito	51	President, Chief Executive Officer and Director
Joel Morganroth, MD	58	Chairman of the Board of Directors and Chief Scientist
Robert S. Brown	48	Senior Vice President, Outsourcing Partnerships
Thomas P. Devine	51	Senior Vice President and Chief Development Officer
Amy Furlong	31	Senior Vice President, Regulatory Compliance
Scott Grisanti	41	Senior Vice President, Business Development and Chief Marketing Officer
Bruce Johnson	53	Senior Vice President and Chief Financial Officer
Jeffrey S. Litwin, MD	46	Senior Vice President and Chief Medical Officer
Anna Marie Pagliaccetti, Esq.	38	Senior Vice President, General Counsel and Secretary
Vincent Renz	47	Senior Vice President, Technology and Consulting and Chief Technology Officer

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.



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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 1976. 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.

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 20 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 eHUB, Inc., an electronic commerce company, from January 2000 to July 2002. From January 1997 to January 2000, Mr. Devine worked for Lockheed Martin, most recently as Director of Systems Integration, 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. From March 1999 to November 1999, Mr. Johnson served as Chief Operating Officer and Chief Financial Officer of HealthAxis.com. From February 1988 to March 1999, Mr. Johnson was employed by N2K Inc., an online music entertainment company, most recently as Senior Vice President, Chief Financial Officer and director. 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 and for the American and National League of Professional Baseball Clubs from April 1995 to March 1999.

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. Prior to joining us, Ms. Pagliaccetti served as Corporate Controller for CDNOW, Inc. and its predecessor companies from December 1993 to March 2000. Ms. Pagliaccetti is licensed to practice law in Pennsylvania and is also a certified public accountant. She is a member of the American and Pennsylvania Bar Associations and the American Institute of Certified Public Accountants.

Mr. Renz has been our Senior Vice President, Technology and Consulting and Chief Technology Officer since January 2000. Mr. Renz served as our Vice President and General Manager of our Clinical Research Technology and Services division from May 1998 to December 1999. Prior to joining us, from January 1998 to May 1998, he worked as a consultant in defining the Client Services infrastructure for the Clinical Research Technology and Services division.



[Back to Contents](#)**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 July 16, 2002, we effected a 3-for-2 split of our common stock. On May 29, 2003, the Company effected a 2-for-1 split of its common stock and on November 26, 2003, the Company effected a 3-for-2 split of its common stock. Market prices in the following table have been restated to reflect these splits of the Company's common stock as if the stock splits had occurred as of December 31, 2001.

<u>Calendar Period</u>	<u>High</u>	<u>Low</u>
2002		
First Quarter	\$ 3.78	\$ 2.24
Second Quarter	5.63	3.28
Third Quarter	6.44	4.27
Fourth Quarter	6.49	3.62
2003		
First Quarter	\$ 9.17	\$ 5.25
Second Quarter	15.67	8.58
Third Quarter	26.37	13.75
Fourth Quarter	33.73	20.67

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 11, 2004, there were approximately 228 holders of our common stock.

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The following selected consolidated financial data is qualified by reference to, and should be read in conjunction with, the consolidated financial statements, including the notes thereto, and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included elsewhere in this Report.

**Consolidated Statements of Operations Data (in thousands, except per share data)**

	<b>Year Ended December 31,</b>				
	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>
Net revenues:					
Licenses	\$ 4,381	\$ 5,189	\$ 1,372	\$ 2,119	\$ 5,738
Services	21,694	22,878	26,625	39,407	61,104
CRO operations	16,710	□	□	□	□
<b>Total net revenues</b>	<b>42,785</b>	<b>28,067</b>	<b>27,997</b>	<b>41,526</b>	<b>66,842</b>
Costs of revenues:					
Cost of licenses	319	721	576	896	658
Cost of					