

ERESEARCHTECHNOLOGY INC /DE/

Form 10-K

March 10, 2006

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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, 2005  
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**  
(Address of Principal Executive Offices)

**19103**  
(Zip Code)

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

**Securities registered pursuant to Section 12(b) of the Act: None**  
**Securities registered pursuant to Section 12(g) of the Act:**

**Title of Class**

**Name of Each Exchange on Which Registered**

Common Stock, \$.01 par value

Nasdaq

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or section 15(d) of the Act.

Yes No

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.

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer" and "large accelerated filer" in Rule 12b-2 of the Exchange Act.

Large accelerated filer      Accelerated filer      Non-accelerated filer

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).  
Yes   No

As of June 30, 2005, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was \$515,160,634 based on the closing sale price as reported on the National Association of Securities Dealers Automated Quotation System National Market System.

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practicable date.

<u>Class</u>	<u>Outstanding at February 28, 2006</u>
Common Stock, \$.01 par value per share	49,193,416 shares

**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 2006 Annual Meeting of Stockholders, to be filed with the Commission pursuant to Regulation 14A.

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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, data interpretation, and new drug, biologic and device application submissions. 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 customers 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 (US) and the United Kingdom (UK). Our international net revenues represented approximately 22%, 18% and 20% of total net revenues for the years ended December 31, 2003, 2004 and 2005, respectively. The majority of our revenues are allocated based upon the profit split transfer pricing methodology.

**Product and Service Offerings**Product/ServicesDescription

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. We provide Cardiac Safety services 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 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 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



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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 may provide cardiac safety equipment to clients to perform the ECG and Holter recordings and to provide electronic ECG collection. We also provide 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 flash card or 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 rendered in a format compliant with the United States Food and Drug Administration's 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



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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 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[])	<p>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.</p> <p>The eResNet includes the following modules:</p>
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.
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

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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 eRC, eDE and eResNet, are available to be licensed over a renewable term (subscription license) in addition to a traditional perpetual license with annual maintenance. All technology offerings may, at our client's option, be hosted by us or 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 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 terms of usability and configurability during 2005. The improvements include new data types, improved navigation, linking to external documents and images, predefined repeat visit schedule capability, and configurable summary screens providing summaries of study information.

Our eDM product was enhanced in several ways during 2005 including the automatic generation of edit checks, import and export of data via XML, expansion of our audit reporting capabilities, and significant performance enhancements related to the study design and generation process.

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. During 2005, our EXPeRT® system was enhanced in several ways, including the ability to generate ECGs in the approved FDA XML format, expansion to our semi-automated workflows and integration with other internal and external data systems. Also during 2005, eRT achieved recognition as the first cardiac safety core laboratory to be certified for submissions of ECG data to the new FDA ECG warehouse.

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### **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, 2005, we had 43 employees engaged in research and development, together with 10 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 \$4.6 million for 2003, \$4.1 million for 2004 and \$4.1 million for 2005.

### **Our Clients**

We serve pharmaceutical, biotechnology and medical device companies as well as CROs. We have contracts with approximately 210 clients that establish the overall contractual relationship between us and our clients. We have Digital ECG Franchise agreements with three clients. We provide our solutions to 34 of the 50 largest pharmaceutical companies globally. In 2005, Novartis AG, at 13%, 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 organizations. As of December 31, 2005, our Business Development Team consisted of 47 sales, marketing and consulting professionals worldwide, which included a direct sales force of 26 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, professional services 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 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



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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 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.

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

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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 subsequent 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 (ICH E14). 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. On May 12, 2005, the ICH ratified and recommended for implementation the cardiac safety monitoring guidance provided in ICH E14 (step 4). The guidance confirms previous guidance reinforcing the need for routine cardiac safety testing as well as Thorough QTc testing for all compounds entering the blood stream commencing early in clinical development to provide maximum guidance for later trials, as well as testing for all compounds in Phase III prior to submission for approval.

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 research and development organization 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 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<sup>®</sup> workflow enabled data handling technology.

eRT has also filed patent applications in Canada, India and the European Patent Office. In addition, eRT filed a continuation-in-part application in the United States Patent and Trademark Office in late 2004 pursuing alternative claim coverage and expects to receive a substantive examination of the application in early 2006. eRT continues to pursue patent protection of new technology advances and production.





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### **Employees**

At December 31, 2005, we had a total of 355 employees, with 288 employees (277 full-time, 11 part-time) at our locations in the United States and 67 employees (62 full-time, 5 part-time) at our location in the United Kingdom. We had 222 employees performing services directly for our clients, 43 employees in research and development, 47 employees in sales and marketing and 43 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 make available on our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission. You may access and print these forms free of charge from our website.

### **ITEM 1A. RISK FACTORS**

The risk factors identified in the cautionary statements below could cause our actual results to differ materially from those suggested in the forward-looking statements appearing elsewhere in this Form 10-K. However, these risk factors are not exhaustive, as new risks emerge from time to time, and it is not possible for management to predict all such risk factors or to assess the impact of all such risk factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Accordingly, forward-looking statements should not be relied upon as a prediction of actual results.

*Extensive governmental regulation of the clinical trial process could require costly modifications to our products, adversely affect prospective clients' willingness to use our products and services and increase competition and reduce our market share.*

We may incur increased expenses or suffer a reduction in revenues if our products and services do not comply with applicable government regulations or if regulations allow more competition in the market place. The FDA has published regulations and guidelines addressing a broad range of matters relating to the use of computerized systems to collect, manage and analyze data from clinical trials. Moreover, electronic data entry, management and analysis of medical information pertaining to subjects in clinical trials will be subject to state and federal government regulations that are not yet finalized. Conforming our products and services to these guidelines or to future changes in regulation could substantially increase our expenses. In the United States and in foreign countries, regulatory authorities have also established other standards for conducting clinical trials leading to the approval of new products with which we must comply. We are subject to these regulations because our products and services assist sponsors and CROs in conducting trials and preparing new drug or device applications. If a regulatory authority concludes that trials were not conducted in accordance with established requirements, it may take a variety of enforcement actions depending upon the nature of the violation and the applicable country. In the United States, these measures may range from issuing a warning letter or seeking injunctive relief or civil penalties to recommending criminal prosecution, which could result in a prohibition of our continued participation in future clinical trials.

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 subsequent 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/

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QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs (ICH E14). 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. On May 12, 2005, the ICH ratified and recommended for implementation the cardiac safety monitoring guidance provided in ICH E14 (step 4). The guidance confirms previous guidance reinforcing the need for routine cardiac safety testing as well as Thorough QTc testing for all compounds entering the blood stream commencing early in clinical development to provide maximum guidance for later trials, as well as testing for all compounds in Phase III prior to submission for approval.

Our clients and prospective clients will be less likely to use our products and services if the products and services do not comply with regulatory requirements in all countries where clinical trials are expected to take place or if we are precluded from participating in clinical trials in countries where trials will be conducted. In addition, changing regulatory requirements could provide an advantage to our competitors if our competitors are able to meet the requirements more rapidly or at lower cost. For example, in the May 12, 2005 ICH release, it was suggested that semi-automated processing of electrocardiograms may be found acceptable in certain instances. Semi-automated processing uses software algorithm-placed measurements that are later adjudicated by a cardiac specialist or physician. While we are positioned to provide semi-automated processing, we have historically been a leader in the industry in manual processing. Our manual processing includes manually derived measurements, using our on screen, high resolution caliper placement system, which are later interpreted by a cardiologist. Drug sponsors have begun to shift towards semi-automated processing, allowing more competitors to compete with us in offering this service and, as a result, we are forced to reduce pricing to maintain our market share. The effect of such actions reduces our revenue and gross profit per transaction. Our results of operations for fiscal 2004 and 2005 were adversely affected by the uncertainty in the clinical research and drug development industry that is due in part to this evolving regulatory guidance, and our results of operations in the future may also be adversely affected if this uncertainty continues. Our failure to maintain revenue and gross profit per transaction may affect our ability to achieve growth in cardiac safety revenues from year to year. If we fail to show growth in cardiac safety revenues, we may not meet the expectations of securities analysts and investors, which would likely cause the market price of our common stock to decline.

*We have several large clients from whom we derive substantial revenue and therefore the loss of even a few of our clients could significantly reduce our revenues.*

We have one client representing more than 10% of our total revenues for 2005. The Franchise Agreement in place for this client expires in 2006. This means we will revert to contract pricing on a per trial basis consistent with our typical master service agreements. If we lose this client or other significant clients and do not replace them with new clients, our revenues will decrease and may not be sufficient to cover our costs. We currently derive and expect to continue to derive a significant portion of our revenues from a limited number of clients.

*Consolidation among our clients could cause us to lose clients, decrease the market for our products and result in a reduction of our revenues.*

Our client base could decline because of consolidation, and we may not be able to expand sales of our products and services to new clients. Consolidation in the pharmaceutical, biotechnology and medical device industries and among CROs has accelerated in recent years, and we expect this trend to continue. In addition, our profitability will suffer if we reduce our prices in response to competitive pressures without achieving corresponding reductions in our expenses.

In addition, new companies or organizations that result from such consolidation may decide that our products and services are no longer needed because of their own internal processes or the use of alternative systems. As these industries consolidate, competition to provide products and services to industry participants will become more intense and the importance of establishing relationships with large industry participants will become greater. These industry participants may try to use their market power to negotiate price reductions for our products and services. Also, if consolidation of larger clients occurs, the combined organization may represent a larger percentage of business for us and, as a result, we are likely to rely more significantly on the combined organization's revenues to continue to achieve growth.

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*If clinical trial sponsors and CROs do not shift from their existing paper-based methods of collecting and managing clinical trial data to an electronic system, we may not achieve the market penetration necessary to grow the business at expected levels.*

If participants conducting clinical trials are unwilling to adopt our technology solutions and new ways of conducting business, our revenues may not be sufficient to achieve the expected growth rate of securities analysts and investors. Our efforts to establish a standardized, electronic process to collect, manage and analyze clinical trial and cardiac safety data are a significant departure from the traditional clinical research process. We estimate that the majority of clinical trials today use manual, paper-based data entry, management and analysis tools. Each clinical trial can involve a multitude of participants, including the sponsor, a CRO, regional site managers, investigators and patients. With so many participants involved in a clinical trial, it may be difficult to convince a sponsor or CRO to accept new methods of conducting a clinical trial. We may not be successful in persuading these participants to change the manner in which they have traditionally operated and to accept our products and services. While we saw some willingness from drug developers to shift from paper-based methods during 2004 and 2005, the adoption is slow.

*If general economic conditions worsen, potential clients may be unwilling to make large capital software purchases or commitments, which could affect our ability to maintain and/or increase license revenues.*

We have seen some resistance by potential clients in making the necessary large capital expenditure to license our software through our traditional perpetual license offering. Despite our efforts to market an annual or otherwise recurring term license, our failure to continue selling perpetual software licenses in the near term may affect our ability to achieve growth in license revenues from year to year. If we fail to show growth in license revenues, we may not meet the expectations of securities analysts and investors, which would likely cause the market price of our common stock to decline. In addition, if we are not successful in selling recurring term licenses, we will not generate the volume of recurring revenues in the future that we are expecting.

*We may fail to maintain revenue and income growth. If we do not maintain revenue and income growth, our stock price is likely to decline and we may not be able to continue to operate.*

Failure to maintain expected growth in profitability could cause the market price of our common stock to decline, affect our ability to raise capital, reduce our cash reserves, limit our capital spending and ultimately cause us to discontinue operating our business.

*Our future operating results are uncertain and may fluctuate. If we fail to meet the expectations of securities analysts and investors, our stock price would likely decline.*

If our operating results in any future period fluctuate significantly, we may not meet the expectations of securities analysts and investors, which would likely cause the market price of our common stock to decline. It is difficult to predict the timing or amount of our revenues because:

- we generate a significant percentage of our revenues from a limited number of clients
- our sales cycles can be lengthy and variable
- Thorough QTc studies are typically of large volume and of short duration

sponsors and CROs may unexpectedly cancel, postpone or reduce the size of clinical trials

We make decisions on operating expenses based on anticipated revenue trends and available resources. We also incur expenses educating and providing information to our client base, including through consultations, without any obligation by our client to purchase our products and services. Because many of our expenses are fixed and we are committed to making a significant investment in our organization and in marketing our products and services, delays in recognizing revenues could cause our operating results to fluctuate from period to period. During most of 2005, we were unable to meet and exceed our guidance. If we fail to generate the contract signings that we expect, we may fail to meet financial guidance that we have provided, or may provide in the future, to the public.

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*We depend entirely on the clinical trial market and a downturn in this market could cause our revenues to decrease.*

Our business depends entirely on the clinical trials that pharmaceutical, biotechnology and medical device companies conduct. Our revenues will decline if there is less competition in the pharmaceutical, biotechnology or medical device industries, which would result in fewer products under development and decreased pressure to accelerate a product approval. Our revenues will also decline if the FDA or similar agencies in foreign countries loosen their requirements, thereby decreasing the complexity of conducting clinical trials. Any other developments that adversely affect the pharmaceutical, biotechnology or medical device industries generally, including product liability claims, new technologies or products or general business conditions, could also decrease the volume of our business. During 2005, three studies for which we contracted to provide Cardiac Safety services were delayed or postponed, resulting in lower than expected revenues and earnings. We could experience this again in the future if there are developments in the clinical trial market that causes a delay in studies.

*Our failure to expand our business or manage growth successfully could disrupt our business operations, increase our costs and delay implementation of our business strategies.*

Difficulties in managing our future growth could disrupt our business operations, increase our costs and delay achievement of our business goals, making it more difficult for us to maintain profitability. Our growth strategy depends on our ability to expand and improve our field sales, marketing and services organization, our operations and our corporate and administrative organizations, both in the United States and throughout the world. In order to grow, we will need to hire additional personnel. There are a limited number of experienced personnel with an adequate knowledge of our industry, and competition for their services is intense. In addition, we may not be able to project the rate or timing of increases in the use of products and services accurately or to expand and upgrade our systems and infrastructure to accommodate the increases. The expansion of our foreign operations also will require us to assimilate differences in foreign business practices, overcome language barriers and hire and retain qualified personnel abroad.

*Our failure to establish and maintain strategic alliances may delay the development of our products and services, cause us to lose clients and prevent us from growing our business, any of which could cause our stock price to decline.*

We have relationships with providers of clinical pharmacology services, hardware and software systems, telecommunications, web-hosting and development, systems integration and website content that support our sales and marketing efforts by satisfying other needs of our existing clients that our solutions do not address and by providing us access to their clients as potential sources of new business. We do not generally have long-term contracts with our strategic partners, so they may cease doing business with us on relatively short notice. We have also built strategic alliances with three of our customers in the form of Digital ECG Franchise agreements. These agreements expire in August 2006, December 2006 and May 2007, respectively. There is no assurance that we will extend these agreements beyond their existing terms. This would mean that we would revert to contract pricing on a per trial basis consistent with our typical master service agreements and potentially lose business from these clients that may affect our future growth.

*We may not be successful in competing against others providing similar products and services, which could reduce our revenues and market share.*

If our products and services do not achieve widespread acceptance by our clients, our revenues and market share will likely decline. Our competitors include other centralized cardiac safety laboratories, CROs, software vendors, and clinical trial data service companies. Our targeted clients, sponsors and CROs may decide to choose other technology-based products and services generated internally by them or from another source. Many of our competitors have substantially greater financial and other resources, greater name recognition and more extensive client bases than we do. In addition, many competitors focus their efforts on providing software or services for discrete aspects of the clinical trial process and may compare favorably to us on those discrete aspects. Further, certain drug development organizations may decide not to outsource all or a significant portion of the cardiac

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safety activities associated with their clinical research programs, which could reduce our revenues and market share.

*We may incur liability as a result of providing Cardiac Safety analysis and interpretation services.*

We provide centralized analysis and interpretation of ECGs in connection with our clients' clinical trials. It is possible that liability may be asserted against us and the physicians who interpret the ECGs for us for failing to accurately diagnose a medical problem indicated by the ECG or for failing to disclose a medical problem to the investigator responsible for the subject being tested. If we are found liable, we may be forced to pay fines and damages and to discontinue a portion of our operations. The contractual protections included in our client contracts and our insurance coverage may not be sufficient to protect us against such liability. If the protections are not adequate, we may be unable to achieve or maintain profitability and our stock price would likely fall.

*The cardiac safety equipment that we own and lease could become obsolete due to technological advances or we may not be able to provide the quantity of equipment needed to service our clients.*

We own and lease equipment, which we provide to our clients to perform cardiac safety procedures. This equipment may become obsolete due to advances in technology and the introduction of newer equipment models prior to the time that we have fully depreciated the asset or fulfilled our lease obligations. This could result in us recording additional expense to write-off the book value or the remaining lease value of the equipment. We are also dependent on a limited number of suppliers to provide the equipment necessary to service our clients and if adequate equipment is not available we may lose clinical clients, resulting in reduced revenues.

*Capacity constraint or system failures could result in the loss of or liability to clients, which could reduce our revenues and increase our expenses.*

In the past, we have been able to staff for increasing workload demands in an expeditious manner. However, there may not be a sufficient and suitable group of potential employees available if rapid growth occurs in a short period of time. If we are unable to hire suitable employees to adequately meet market demand for QTC studies, it could affect our ability to bid on this business or to meet existing contractual turnaround times.

If our clients experience any significant level of problems with our technology, we may become liable to those clients, we may be unable to persuade our clients to change from a manual, paper-based process and we may lose clients. The success of our products and services depends on the ability to protect against:

- software or hardware malfunctions that interrupt operation of our applications or cause loss of data integrity
- power loss or telecommunications failures
- overloaded systems
- human error
- natural disasters

In addition, when we offer our software products as an application service provider, our network infrastructure may be vulnerable to computer viruses, break-ins and similar disruptive problems caused by our clients or other Internet users. This could also lead to delays, loss of data, interruptions or cessation of service to our clients for which we may be liable. There is no current technology that provides absolute protection against these events. In addition, we may find that the cost to develop or incorporate technology into our products that provides the maximum protection against these problems outweighs the incremental benefits of providing such enhanced protection.

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*Our software products are complex and may contain undetected software errors, which could lead to an increase in our costs or a reduction in our revenues.*

The occurrence of hardware and software errors, whether caused by our solutions or another vendor's products, could:

- cause sales of our solutions to decrease and our revenues to decline
- cause us to incur significant warranty and repair costs
- divert the attention of our technical personnel away from product development efforts
- cause significant client relations problems

Complex software products such as those included in our technology solutions frequently contain undetected errors when first introduced or as new versions are released. In addition, we combine our solutions with software and hardware products from other vendors. As a result, we may experience difficulty in identifying the source of an error.

*Rapidly changing technology may impair our ability to develop and market our solutions and cause us to become less competitive.*

The marketplace for our software products is increasingly driven by demands for ease of use and effective performance for end users of the system. We depend on continued focus on product improvements in this area in order to remain competitive.

Our failure to continuously offer competitive products and services could cause us to lose clients and prevent us from successfully marketing our solutions to prospective clients. As a result, our revenues would likely decline. Because our business relies on technology, we are susceptible to:

- rapid technological change
- changing client needs
- frequent new product introductions
- evolving industry standards

As the Internet, computer and software industries continue to experience rapid technological change, we must quickly modify our solutions to adapt to such changes. Currently, the EDC industry is reevaluating its technology needs for the future. The demands of operating in such an environment may delay or prevent our development and introduction of new or enhanced products and services that continually meet changing market demands and that keep pace with evolving industry standards. We have experienced development delays in the past and may experience similar or more significant delays in the future. In addition, competitors may develop products superior to our solutions, which could make our products obsolete.

*We depend on certain key executives. If we lose the services of any of these executives, our operations could be disrupted, we could incur additional expenses and our ability to expand our operations could be impeded, particularly if we are not able to recruit a suitable replacement in a timely manner.*

The loss of the services of one or more of our key executives could negatively affect our ability to achieve our business goals. In December 2005 and February 2006, we announced the pending retirements of our Executive Vice President and Chief Financial Officer and our President and Chief Executive Officer, respectively. Our future performance will depend significantly on our ability to replace these two positions with talented individuals and the continued service and performance of all of our remaining executives, particularly Dr. Joel Morganroth, our Chairman of the Board of Directors. We also depend on our key technical, client support, sales and other managerial employees. We believe that it would be costly and time consuming to find suitable replacements for all these employees, including the replacements for our Executive Vice President and Chief Financial Officer and our President and Chief Executive Officer.



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*If we are unable to protect our proprietary technology or maintain our technological advantages, we may lose our intellectual property rights and become less competitive.*

If we fail to protect our intellectual property from infringement, other companies may use our intellectual property to offer competitive products at lower prices. If we fail to compete effectively against these companies, we could lose clients and experience a decline in sales of our solutions. To protect our intellectual property rights, we rely on a combination of copyright and trade secret laws and restrictions on disclosure. In addition, in 2004 we were issued a U.S. Patent on over 50 claims directed to various features of eRT's EXPeRT® workflow enabled data handling technology. Despite our efforts to protect our proprietary rights, unauthorized parties may copy or otherwise obtain and use our products and technology. In addition, our U.S. Patent could be successfully challenged as invalid. Monitoring unauthorized use of our solutions is difficult and the steps we have taken may not prevent unauthorized use of our technology, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States.

*Third parties may claim that we infringe upon their intellectual property rights, which could result in the loss of our rights, subject us to liability and divert management attention.*

Although we are not currently involved in any intellectual property litigation, we may be a party to litigation in the future either to protect our intellectual property or as a result of an alleged infringement by us of the intellectual property of others. These claims and any resulting litigation could subject us to significant liability or invalidate our ownership rights in the technology used in our solutions. As a result, we may have to stop selling our solutions. Litigation, regardless of the merits of the claim or outcome, could consume a great deal of our time and money and would divert management time and attention away from our core business.

Any potential intellectual property litigation also could force us to do one or more of the following:

- stop using the challenged intellectual property or selling our products or services that incorporate it
- obtain a license to use the challenged intellectual property or to sell products or services that incorporate it, which could be costly or unavailable
- redesign those products or services that are based on or incorporate the challenged intellectual property, which could be costly and time consuming or could adversely affect the functionality and market acceptance of our products

If we must take any of the foregoing actions, we may be unable to sell our solutions, which would substantially reduce our revenues.

*Third parties have made claims for damages against the Company and may continue to do so, which could result in an unfavorable settlement or judgment against us.*

We are currently named as a defendant in an action for damages. Although we believe the claim against us is without merit and we intend to vigorously defend ourselves, we may be unsuccessful in our defense efforts, which would result in unfavorable settlement costs or monetary judgments against us. Litigation, regardless of the merits of the claim or outcome, consumes a great deal of our time and money and often diverts management time and attention away from our core business. In addition, unsuccessful litigation could reduce our cash reserves, cause the market price of our common stock to decline and ultimately cause us to discontinue operating our business.

*Our international operations expose us to additional risks.*

A key element of our business strategy is to expand our international operations. We face a number of risks and expenses that are inherent in operating in foreign countries and, accordingly, our international operations may not achieve profitability consistently each year. The risks to us from our international operations include:

- Government regulations
- Trade restrictions
- Burdensome foreign taxes





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- Exchange rate controls and currency exchange rate fluctuations
- Political and economic instability
- Varying technology standards
- Difficulties in staffing and managing foreign operations

We are subject to a variety of government regulations in the countries where we market our products and services. We currently operate in the United Kingdom through a foreign subsidiary and may operate in the future in other countries through additional foreign subsidiaries. If we form foreign subsidiaries outside of the United Kingdom, we may need to withhold taxes on earnings or other payments they distribute to us. Generally, we can claim a foreign tax credit against our federal income tax expense for these taxes. However, the United States tax laws have a number of limitations on our ability to claim that credit or to use any foreign tax losses, which could result in higher payment by us of taxes in the United States. We may also need to include our share of our foreign subsidiaries' earnings in our income even if the subsidiaries do not distribute money to us. As a result, less cash would be available to us in the United States.

Our global operations may involve transactions in a variety of currencies. Fluctuations in currency exchange rates could reduce our reported revenues or increase our reported expenses. We currently do not utilize hedging instruments.

The agreements that we sign with clients outside the United States may be governed by the laws of the countries where we provide our products and services. We may also need to resolve any disputes under these agreements in the courts or other dispute resolution forums in those countries. This could be expensive or could distract management's attention away from our core business.

#### **ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

#### **ITEM 2. PROPERTIES**

Our corporate headquarters are located at 30 South 17th Street, Philadelphia, Pennsylvania, where we lease approximately 39,000 square feet. 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 lease approximately 18,000 square feet of office space in Peterborough, United Kingdom, which expires in June 2013.

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, MD, et al. (Civ. Act. No. MICV 2003-01728)). The complaint alleged 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 reimbursed our company for the cost of our defense. Dr. Kleiman was dismissed as a defendant in August 2003 and our company was dismissed, with prejudice, as a defendant in May 2005.

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 amended



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complaint alleges breach of contract, unjust enrichment and promissory estoppel. The plaintiffs also sought 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. In January 2006, a summary judgment was ordered in our favor and against the plaintiffs on all counts of the amended complaint. A notice of appeal was filed by the plaintiffs in February 2006. We will continue 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:

<b>Name</b>	<b>Age</b>	<b>Position</b>
Joseph A. Esposito	53	President, Chief Executive Officer and Director
Joel Morganroth, MD	60	Chairman of the Board of Directors
Thomas P. Devine	53	Executive Vice President and Chief Development Officer
Amy Furlong	33	Executive Vice President, Cardiac Safety
Scott Grisanti	43	Executive Vice President and Chief Marketing Officer
Bruce Johnson	55	Executive Vice President and Chief Financial Officer
Jeffrey S. Litwin, MD	48	Executive Vice President and Chief Medical Officer
Vincent Renz	49	Executive Vice President and Chief Technology Officer
Robert S. Brown	50	Senior Vice President, Outsourcing Partnerships
Anna Marie Pagliaccetti, Esq.	40	Senior Vice President, General Counsel and Secretary
George Tiger	46	Senior Vice President, International Sales and Operations

Mr. Esposito has served as our President and Chief Executive Officer since 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. In 2002, Mr. Esposito was awarded The Ellis Island Medal of Honor for outstanding citizenship, individual achievement, and encouragement of cultural unity. He has over 31 years experience in technology, working closely with pharmaceutical companies in the areas of clinical research, supply chain management and regulatory document management. In February 2006, we announced Mr. Esposito plans to retire during 2006 from his positions as our President and Chief Executive Officer and as a director.

Dr. Morganroth has served as the Chairman of our Board of Directors since 1999 and a member of our Board of Directors since 1997. He served as our Chief Scientist from March 2001 to December 2005 and 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.

Mr. Devine has been our Executive Vice President and Chief Development Officer since December 2005. Previously, he served as 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.

Ms. Furlong has been our Executive Vice President, Cardiac Safety since December 2005. Previously, she served as our Senior Vice President, Regulatory Compliance since January 2004. From February 2001 to January 2004, Ms. Furlong served as our Vice President, Regulatory Compliance and from February 1999 to February 2001, she served as our Senior Director, Regulatory Compliance.



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Mr. Grisanti has been our Executive Vice President and Chief Marketing Officer since December 2005. Previously, he served as our Senior Vice President, Business Development and Chief Marketing Officer since October 2000.

Mr. Johnson has been our Executive Vice President and Chief Financial Officer since December 2005. Previously, he served as 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. In December 2005, we announced Mr. Johnson's plans to retire from his positions as our Executive Vice President and Chief Financial Officer during 2006.

Dr. Litwin is a cardiologist and has been our Executive Vice President and Chief Medical Officer since December 2005. Previously, he served as our Senior Vice President and Chief Medical Officer since July 2000.

Mr. Renz has been our Executive Vice President and Chief Technology Officer since December 2005. Previously, he served as our Senior Vice President, Client Services and Chief Technology Officer since April 2004. From January 2000 to March 2004, Mr. Renz served as our Senior Vice President, Technology and Consulting and Chief Technology Officer. Mr. Renz has over 20 years of experience in developing and implementing information technology products and services.

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. Mr. Brown has been employed with us for over 23 years.

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. Tiger has been our Senior Vice President, International Sales and Operations since December 2005. Previously, Mr. Tiger served as our Senior Vice President, International Operations from July 2004 to December 2005, Vice President, International Business Development from August 2002 to July 2004 and as Director of Business Development from January 2001 to August 2002.

[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 May 27, 2004, we effected a 3-for-2 split of our common stock. Market prices in the following table have been restated to reflect this split of our common stock as if the stock split had occurred as of December 31, 2003.

<u>Calendar Period</u>	<u>High</u>	<u>Low</u>
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
2005		
First Quarter	\$ 16.80	\$ 10.01
Second Quarter	13.92	10.11
Third Quarter	16.25	12.86
Fourth Quarter	16.23	12.76

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 February 28, 2006, there were 60 record holders of our common stock.

We announced on May 3, 2005 that our Board of Directors had authorized the purchase of up to an additional 10 million shares of our common stock, which extended the stock buy-back program previously announced to authorize the repurchase of a total of 12.5 million shares. The current stock buy-back program was originally announced in April 2004 and extended to 2.5 million shares in October 2004. Through December 31, 2005, we have repurchased 3.8 million shares of the 12.5 million shares approved for repurchase. The following table provides information regarding the stock buy-back activity during the fiscal quarter ended December 31, 2005:

**Issuer Purchases of Equity Securities**

<u>Period</u>	<u>(a) Total Number of Shares Purchased</u>	<u>(b) Average Price Paid per Share</u>	<u>(c) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs</u>	<u>(d) Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs</u>
October 2005	□	\$ □	□	9,815,400
November 2005	850,000	\$ 13.96	850,000	8,965,400
December 2005	250,000	\$ 13.97	250,000	8,715,400
Total	1,100,000	\$ 13.96	1,100,000	

[Back to Contents](#)**ITEM 6. SELECTED FINANCIAL DATA**

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 Form 10-K.

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

	Year Ended December 31,				
	2001	2002	2003	2004	2005
Net revenues:					
Licenses	\$ 1,372	\$ 2,119	\$ 5,738	\$ 9,803	\$ 6,063
Services	23,355	31,344	46,791	76,340	59,712
Site support	3,270	8,063	14,313	23,250	21,072
<b>Total net revenues</b>	<b>27,997</b>	<b>41,526</b>	<b>66,842</b>	<b>109,393</b>	<b>86,847</b>
Costs of revenues:					
Cost of licenses	576	896	658	664	436
Cost of services	11,046	12,816	17,473	24,124	24,337
Cost of site support	1,342	4,301	6,610	11,486	13,965
<b>Total costs of revenues</b>	<b>12,964</b>	<b>18,013</b>	<b>24,741</b>	<b>36,274</b>	<b>38,738</b>
<b>Gross margin</b>	<b>15,033</b>	<b>23,513</b>	<b>42,101</b>	<b>73,119</b>	<b>48,109</b>
Operating expenses:					
Selling and marketing	5,427	6,719	7,763	9,391	9,122
General and administrative	5,188	5,695	6,804	10,276	11,458
Research and development	4,865	4,256	4,564	4,090	4,093
<b>Total operating expenses</b>	<b>15,480</b>	<b>16,670</b>	<b>19,131</b>	<b>23,757</b>	<b>24,673</b>
Operating income (loss)	(447)	6,843	22,970	49,362	23,436
Other income, net	941	868	310	863	936
Investment impairment charge	(5,686)	□	□	□	□
Gain on sale of domestic CRO operation	1,422	35	□	□	□
<b>Income (loss) before income taxes and minority interest</b>	<b>(3,770)</b>	<b>7,746</b>	<b>23,280</b>	<b>50,225</b>	<b>24,372</b>
Income tax provision (benefit)	(112)	1,596	8,817	20,501	9,007
Minority interest dividend(1)	116	□	□	□	□
<b>Net income (loss)</b>	<b>\$ (3,774)</b>	<b>\$ 6,150</b>	<b>\$ 14,463</b>	<b>\$ 29,724</b>	<b>\$ 15,365</b>
Basic net income (loss) per share	\$ (0.08)	\$ 0.13	\$ 0.29	\$ 0.58	\$ 0.31
Diluted net income (loss) per share	\$ (0.08)	\$ 0.12	\$ 0.27	\$ 0.54	\$ 0.29

**Consolidated Balance Sheet Data (in thousands)**

	December 31,				
	2001	2002	2003	2004	2005
	\$ 18,430	\$ 26,750	\$ 51,922	\$ 64,964	\$ 52,001



Cash, cash equivalents and short-term investments					
Working capital	20,689	24,693	45,777	53,492	45,795
Total assets	41,000	53,392	91,978	116,895	104,766
Treasury stock	(3,229)	(3,229)	(3,390)	(31,555)	(56,387)
Total stockholders' equity	32,792	40,580	69,259	86,854	79,973

(1) Represents a minority interest dividend earned by a preferred stockholder.

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## **ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

### **Cautionary Statement for Forward-Looking Information**

The following discussion and analysis should be read in conjunction with our consolidated financial statements and the related notes to the consolidated financial statements appearing elsewhere in this Form 10-K. The following discussion includes a number of forward-looking statements made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995 that reflect our current views with respect to future events and financial performance. We use words such as anticipate, believe, expect, intend and similar expressions to identify forward-looking statements. You should not place undue reliance on these forward-looking statements, which apply only as of the date of this report. These forward-looking statements are subject to risks and uncertainties such as competitive factors, technology development, market demand and our ability to obtain new contracts and accurately estimate net revenues due to uncertain regulatory guidance, variability in size, scope and duration of projects, and internal issues of the sponsoring client. Such risks and uncertainties could cause actual results to differ materially from historical results or future predictions. Further information on potential factors that could affect our financial results can be found in Item 1A "Risk Factors" in this Form 10-K.

### **Overview**

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, data interpretation, and new drug, biologic and device application submissions. 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. 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.

Our license revenues consist of license fees for perpetual license sales and monthly and annual license sales. Our services revenues consist of Cardiac Safety services, technology consulting and training services and software maintenance services. Our site support revenue consists of cardiac safety equipment rentals and sales along with related supplies and freight.

We enter into contracts to sell our products and services and, while the majority of our sales agreements contain standard terms and conditions, there are agreements that contain multiple elements or non-standard terms and conditions. As a result, significant contract interpretation is sometimes required to determine the appropriate accounting, including whether the deliverables specified in a multiple element arrangement should be treated as separate units of accounting for revenue recognition purposes and, if so, how the price should be allocated among the deliverable elements and when to recognize revenue for each element. We recognize revenue for delivered elements only when the fair values of undelivered elements are known, uncertainties regarding client acceptance are resolved and there are no client-negotiated refund or return rights affecting the revenue recognized for delivered elements.

Cost of licenses consists primarily of applications service provider (ASP) fees for those clients that choose hosting, the cost of producing compact disks and related documentation and royalties paid to third parties in connection with their contributions to our product development. Cost of services includes the cost of Cardiac Safety services and the cost of technology consulting, training and maintenance services. Cost of Cardiac Safety services consists primarily of direct costs related to our centralized Cardiac Safety services and includes wages,



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depreciation and other direct operating costs. Cost of technology consulting, training and maintenance services consists primarily of wages, fees paid to outside consultants and other direct operating costs related to our consulting and client support functions. Cost of site support consists primarily of wages, cardiac safety equipment rent and depreciation, related supplies, cost of equipment sold, shipping expenses and other direct operating costs. Selling and marketing expenses consist primarily of wages and commissions paid to sales personnel, travel expenses and advertising and promotional expenditures. General and administrative expenses consist primarily of wages and direct costs for our finance, administrative, corporate information technology, legal and executive management functions, in addition to professional service fees and corporate insurance. Research and development expenses consist primarily of wages paid to our product development staff, costs paid to outside consultants and direct costs associated with the development of our technology products.

We conduct our operations through offices in the United States (US) and the United Kingdom (UK). Our international net revenues represented approximately 22%, 18% and 20% of total net revenues for the years ended December 31, 2003, 2004 and 2005, respectively. The majority of our revenues are allocated among our geographic segments based upon the profit split transfer pricing methodology. The international net revenues as a percentage of total net revenues reflect the application of the change in transfer pricing methodology, as discussed in Note 5 in the Notes to Consolidated Financial Statements included elsewhere in this Form 10-K, as if the changes were in effect as of January 1, 2004. See Note 11 in the Notes to Consolidated Financial Statements elsewhere in this Form 10-K for a detailed discussion of revenue recognition among the geographic segments.

## Results of Operations

### *Executive Overview*

2005 was characterized by uncertainty in the clinical research and drug development industry, due in part to evolving regulatory guidance concerning cardiac safety. Regulatory bodies, such as the United States Food and Drug Administration (FDA) and the International Conference on Harmonization (ICH), provide guidance on the clinical trial process. This guidance can have a significant influence on the decisions made by our clients and potential clients regarding the use of our services. We believe that regulatory uncertainty delayed new contract signings and extended the time for initiation of new studies. We believe that our results of operations for 2005 were adversely affected as a result of this uncertainty. Revenue, net income and operating cash flow for the year all decreased substantially as compared to 2004. Because we believed that the adverse impact of the regulatory uncertainty was temporary, we did not reduce our infrastructure which led to lower gross margins and operating income in 2005 as compared to 2004.

On May 12, 2005, the International Committee on Harmonization (ICH) ratified and recommended implementation (step 4) of the cardiac safety monitoring guidance provided in ICH E14: The Clinical Evaluation of QT/QTc Interval Prolongation and Proarrhythmic Potential for Non-Antiarrhythmic Drugs. The guidance confirmed previous guidance reinforcing the need for routine cardiac safety testing as well as Thorough QTc testing for all compounds entering the blood stream commencing early in clinical development to provide maximum guidance for later trials, as well as testing for all compounds in Phase III prior to submission for approval. We believe that the ICH E14 guidance has, to some extent, alleviated the regulatory uncertainty that has existed. We announced record bookings of \$32.0 million in the third quarter of 2005 and \$39.7 million in the fourth quarter of 2005. We believe that the higher level of bookings in the third and fourth quarters of 2005, as compared to the first and second quarters of 2005, was partially in response to the issuance of the ICH E14 guidance. The majority of the revenues related to the third and fourth quarter bookings will occur in 2006 and beyond.

Our manual processing of ECGs includes manually derived measurements, using our on screen, high resolution caliper placement system, which are later interpreted by a cardiologist. Drug sponsors have begun to shift certain studies towards semi-automated processing allowing more competitors to compete with us and, as a result, we offer semi-automated processing services at reduced pricing to maintain our market share.

During 2005, we purchased approximately 1.8 million shares of our stock for approximately \$24.8 million under a stock buy-back program authorized by our Board of Directors.

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The following table presents certain financial data as a percentage of total net revenues:

	<b>Year Ended December 31,</b>		
	<b>2003</b>	<b>2004</b>	<b>2005</b>
<b>Net revenues:</b>			
Licenses	8.6%	9.0%	7.0%
Services	70.0	69.8	68.8
Site support	21.4	21.2	24.2
<b>Total net revenues</b>	<b>100.0</b>	<b>100.0</b>	<b>100.0</b>
<b>Costs of revenues:</b>			
Cost of licenses	1.0	0.6	0.5
Cost of services	26.1	22.1	28.0
Cost of site support	9.9	10.5	16.1
<b>Total costs of revenues</b>	<b>37.0</b>	<b>33.2</b>	<b>44.6</b>
<b>Gross margin</b>	<b>63.0</b>	<b>66.8</b>	<b>55.4</b>
<b>Operating expenses:</b>			
Selling and marketing	11.6	8.6	10.5
General and administrative	10.2	9.4	13.2
Research and development	6.8	3.7	4.7
<b>Total operating expenses</b>	<b>28.6</b>	<b>21.7</b>	<b>28.4</b>
<b>Operating income</b>	<b>34.4</b>	<b>45.1</b>	<b>27.0</b>
<b>Other income, net</b>	<b>0.4</b>	<b>0.8</b>	<b>1.1</b>
<b>Income before income taxes</b>	<b>34.8</b>	<b>45.9</b>	<b>28.1</b>
<b>Income tax provision</b>	<b>13.2</b>	<b>18.7</b>	<b>10.4</b>
<b>Net income</b>	<b>21.6%</b>	<b>27.2%</b>	<b>17.7%</b>

[Back to Contents](#)**Year Ended December 31, 2005 Compared to the Year Ended December 31, 2004**

The following table presents statements of operations data with product line detail (in thousands):

	<b>Year Ended December 31,</b>			
	<b>2004</b>	<b>2005</b>		
<b>Licenses:</b>				
Net revenues	\$ 9,803	\$ 6,063	\$ (3,740)	(38.2%)
Costs of revenues	664	436	(228)	(34.3%)
<b>Gross margin</b>	<b>\$ 9,139</b>	<b>\$ 5,627</b>	<b>\$ (3,512)</b>	<b>(38.4%)</b>
<b>Services:</b>				
<b>Cardiac Safety</b>				
Net revenues	\$ 68,270	\$ 52,533	\$ (15,737)	(23.1%)
Costs of revenues	20,316	21,420	1,104	5.4%
<b>Gross margin</b>	<b>\$ 47,954</b>	<b>\$ 31,113</b>	<b>\$ (16,841)</b>	<b>(35.1%)</b>
<b>Technology consulting and training</b>				
Net revenues	\$ 3,628	\$ 2,429	\$ (1,199)	(33.0%)
Costs of revenues	2,692	1,874	(818)	(30.4%)
<b>Gross margin</b>	<b>\$ 936</b>	<b>\$ 555</b>	<b>\$ (381)</b>	<b>(40.7%)</b>
<b>Software maintenance</b>				
Net revenues	\$ 4,442	\$ 4,750	\$ 308	6.9%
Costs of revenues	1,116	1,043	(73)	(6.5%)
<b>Gross margin</b>	<b>\$ 3,326</b>	<b>\$ 3,707</b>	<b>\$ 381</b>	<b>11.5%</b>
<b>Total services</b>				
Net revenues	\$ 76,340	\$ 59,712	\$ (16,628)	(21.8%)
Costs of revenues	24,124	24,337	213	0.9%
<b>Gross margin</b>	<b>\$ 52,216</b>	<b>\$ 35,375</b>	<b>\$ (16,841)</b>	<b>(32.3%)</b>
<b>Site support:</b>				
Net revenues	\$ 23,250	\$ 21,072	\$ (2,178)	(9.4%)
Costs of revenues	11,486	13,965	2,479	21.6%
<b>Gross margin</b>	<b>\$ 11,764</b>	<b>\$ 7,107</b>	<b>\$ (4,657)</b>	<b>(39.6%)</b>
<b>Total</b>				
Net revenues	\$ 109,393	\$ 86,847	\$ (22,546)	(20.6%)
Costs of revenues	36,274	38,738	2,464	6.8%
<b>Gross margin</b>	<b>73,119</b>	<b>48,109</b>	<b>(25,010)</b>	<b>(34.2%)</b>
<b>Operating expenses:</b>				

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Selling and marketing	9,391	9,122	(269)	(2.9%)
General and administrative	10,276	11,458	1,182	11.5%
Research and development	4,090	4,093	3	0.1%
	<u>          </u>	<u>          </u>	<u>          </u>	
Total operating expenses	23,757	24,673	916	3.9%
	<u>          </u>	<u>          </u>	<u>          </u>	
Operating income	49,362	23,436	(25,926)	(52.5%)
Other income, net	863	936	73	8.5%
	<u>          </u>	<u>          </u>	<u>          </u>	
Income before income taxes	50,225	24,372	(25,853)	(51.5%)
Income tax provision	20,501	9,007	(11,494)	(56.1%)
	<u>          </u>	<u>          </u>	<u>          </u>	
Net income	\$ 29,724	\$ 15,365	\$ (14,359)	(48.3%)
	<u>          </u>	<u>          </u>	<u>          </u>	

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The following table presents costs of revenues as a percentage of related net revenues and operating expenses as a percentage of total net revenues:

	<b>Year Ended December 31,</b>		<b>Increase (Decrease)</b>
	<b>2004</b>	<b>2005</b>	
Cost of licenses	6.8%	7.2%	0.4%
Cost of services:			
Cardiac Safety	29.8%	40.8%	11.0%
Technology consulting and training	74.2%	77.2%	3.0%
Software maintenance	25.1%	22.0%	(3.1%)
Total cost of services	31.6%	40.8%	9.2%
Cost of site support	49.4%	66.3%	16.9%
Total costs of revenues	33.2%	44.6%	11.4%
Operating expenses:			
Selling and marketing	8.6%	10.5%	1.9%
General and administrative	9.4%	13.2%	3.8%
Research and development	3.7%	4.7%	1.0%

License revenues decreased primarily due to a decline in the number of licenses sold and a decrease in the average license revenue for each license sold. The decrease in the average license revenue was largely the result of a change in the mix of the type of licenses sold and the number of users for each license.

The decrease in Cardiac Safety service revenues was primarily due to a decrease in transactions performed and a decrease in average revenue per transaction. The decrease in sales volume in 2005 was partially attributable to a slowdown in contract signings in the second half of 2004 and the first half of 2005, delays in certain studies as well as a decrease in 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. As a result, revenues resulting from Thorough QTc studies are more difficult to predict. We believe that regulatory uncertainty delayed new contract signings and extended the time for initiation of new studies. The decrease in average revenue per transaction was largely due to the impact of increased activity in franchise accounts and semi-automated processing, which generally include lower fees per transaction than other studies, as well as competitive pricing adjustments.

Technology consulting and training revenues decreased primarily due to a reduction in consulting and configuration for Clinical Data Management software products. Many of the license sales in 2005 required limited consulting services due to the nature of the licenses sold.

Software maintenance revenues increased due to software licenses sold during and after 2004, which increased the number of total active licenses and their related maintenance fees.

Site support revenue decreased primarily due to a decrease in the sale of cardiac safety equipment (2004 included an unusually large sale transaction) as well as a decrease in revenue from the rental of cardiac safety equipment, which our clients use to perform cardiac safety procedures. This was driven largely by a reduction in the average revenue per equipment unit due to competitive pricing in the cardiac safety services market.

The decrease in cost of licenses was primarily due to a royalty paid in 2004 to a third-party software developer related to the sale of one of the perpetual licenses as well as a decrease in ASP hosting fees. The increase in cost of licenses as a percentage of license revenues was due to the decrease in perpetual license revenues which have very little incremental cost of sales, such that revenue reductions lead to minimal cost savings.

The increase in the cost of Cardiac Safety services, both in absolute terms and as a percentage of Cardiac Safety revenues, was primarily due to an increase in labor, depreciation and increased facilities and other costs associated with expanding capabilities to meet the past and expected future growth in Cardiac Safety service revenues. Partially offsetting these increases was a reduction in incentive bonuses due to higher targets set for the first half of 2005 that were not achieved, a reduction in amortization expense related to internal use software costs and a reduction in recruitment expenses. See [Liquidity and Capital Resources] for additional information





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related to internal use software. Additionally, the increase in the cost of Cardiac Safety services as a percentage of Cardiac Safety service revenues was due to the fact that some of the costs do not necessarily increase or decrease in direct relation with changes in revenue.

The decrease in the cost of technology consulting and training services was primarily due to a reduction in incentive bonuses due to higher targets set for the first half of 2005 that were unmet, a reduction in third-party consulting costs that was partially attributable to the decrease in related revenue, higher employee benefits costs in 2004 in connection with stock option exercises and a decrease in other labor costs. The increase in the cost of technology consulting and training services as a percentage of technology consulting and training service revenues was due to the fact that some of the costs do not necessarily increase or decrease in direct relation with changes in revenue.

The increase in the cost of site support, both in absolute terms and as a percentage of site support revenues, was due primarily to an increase in depreciation and rental costs associated with cardiac safety rental equipment and other costs associated with expanding capabilities to meet the past and expected growth in site support activities, including the addition of new dedicated site support facilities in both the US and UK during the second half of 2004. The increase in the cost of site support as a percentage of site support revenues was also due to the fact that some of the costs do not necessarily increase or decrease in direct relation with changes in revenue.

The decrease in selling and marketing expenses was primarily due to lower commissions that resulted from a decrease in commissionable revenue and the conversion of certain business development directors from incentive compensation based upon commission to incentive compensation based upon bonus. In the second half of 2005, performance against bonus targets improved which resulted in an increase in bonus expense, which partially offset the commission expense reduction. Additionally, labor cost increases in 2005 partially offset the commission expense reduction. The increase in selling and marketing expenses as a percentage of total net revenues was due to maintaining other selling and marketing expenditures, including labor, despite the decrease in total net revenues.

The increase in general and administrative expenses, both in absolute terms and as a percentage of total net revenues, was due primarily to higher labor costs due to new hires, an increase in charitable contributions in 2005, and increases in professional and board fees, depreciation, equipment, insurance and telephone expenses. These increases were partially offset by a reduction in incentive bonuses due to higher targets in the first half of 2005 that were not achieved as well as lower audit fees due to the high cost of the initial attestation work in 2004 on internal controls in accordance with the Sarbanes-Oxley Act. The increase in general and administrative expenses as a percentage of total net revenues was also due to the decrease in net revenues and the fact that general and administrative expenses do not necessarily increase or decrease with changes in revenues.

Other income, net, consisted primarily of interest income realized from our cash, cash equivalents and investments as well as foreign exchange gains, net of interest expense related to capital lease obligations, foreign exchange losses and an impairment charge related to a cost basis investment. Other income, net increased primarily due to a shift to higher yielding money market investments and a decrease in interest expense related to capital leases in 2005. These increases were partially offset by foreign exchange losses in 2005 as well as an impairment charge in the first quarter of 2005 related to a cost basis investment.

Our effective tax rate was 40.8% and 37.0% for the years ended December 31, 2004 and 2005, respectively. The tax rate for the year ended December 31, 2005 included a net income tax benefit of approximately \$347,000 related to the recovery of prior year state taxes due to a change in our transfer pricing methodology.

[Back to Contents](#)**Year Ended December 31, 2004 Compared to the Year Ended December 31, 2003**

The following table presents statements of operations data with product line detail (in thousands):

	<b>Year Ended December 31,</b>		<b>Increase (Decrease)</b>	
	<b>2003</b>	<b>2004</b>		
<b>Licenses</b>				
Net revenues	\$ 5,738	\$ 9,803	\$ 4,065	70.8%
Costs of revenues	658	664	6	0.9%
<b>Gross margin</b>	<b>\$ 5,080</b>	<b>\$ 9,139</b>	<b>\$ 4,059</b>	<b>79.9%</b>
<b>Services:</b>				
<b>Cardiac Safety</b>				
Net revenues	\$ 38,986	\$ 68,270	\$ 29,284	75.1%
Costs of revenues	13,490	20,316	6,826	50.6%
<b>Gross margin</b>	<b>\$ 25,496</b>	<b>\$ 47,954</b>	<b>\$ 22,458</b>	<b>88.1%</b>
<b>Technology consulting and training</b>				
Net revenues	\$ 3,800	\$ 3,628	\$ (172)	(4.5%)
Costs of revenues	2,897	2,692	(205)	(7.1%)
<b>Gross margin</b>	<b>\$ 903</b>	<b>\$ 936</b>	<b>\$ 33</b>	<b>3.7%</b>
<b>Software maintenance</b>				
Net revenues	\$ 4,005	\$ 4,442	\$ 437	10.9%
Costs of revenues	1,086	1,116	30	2.8%
<b>Gross margin</b>	<b>\$ 2,919</b>	<b>\$ 3,326</b>	<b>\$ 407</b>	<b>13.9%</b>
<b>Total services</b>				
Net revenues	\$ 46,791	\$ 76,340	\$ 29,549	63.2%
Costs of revenues	17,473	24,124	6,651	38.1%
<b>Gross margin</b>	<b>\$ 29,318</b>	<b>\$ 52,216</b>	<b>\$ 22,898</b>	<b>78.1%</b>
<b>Site support:</b>				
Net revenues	\$ 14,313	\$ 23,250	\$ 8,937	62.4%
Costs of revenues	6,610	11,486	4,876	73.8%
<b>Gross margin</b>	<b>\$ 7,703</b>	<b>\$ 11,764</b>	<b>\$ 4,061</b>	<b>52.7%</b>
<b>Total</b>				
Net revenues	\$ 66,842	\$ 109,393	\$ 42,551	63.7%
Costs of revenues	24,741	36,274	11,533	46.6%
<b>Gross margin</b>	<b>42,101</b>	<b>73,119</b>	<b>31,018</b>	<b>73.7%</b>
<b>Operating expenses:</b>				
Selling and marketing	7,763	9,391	1,628	21.0%
General and administrative	6,804	10,276	3,472	51.0%
Research and development	4,564	4,090	(474)	(10.4%)

Total operating expenses	19,131	23,757	4,626	24.2%
Operating income	22,970	49,362	26,392	114.9%
Other income, net	310	863	553	178.4%
Income before income taxes	23,280	50,225	26,945	115.7%
Income tax provision	8,817	20,501	11,684	132.5%
Net income	\$ 14,463	\$ 29,724	\$ 15,261	105.5%

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The following table presents costs of revenues as a percentage of related net revenues and operating expenses as a percentage of total net revenues:

	<b>Year Ended December 31,</b>		<b>Increase (Decrease)</b>
	<b>2003</b>	<b>2004</b>	
Cost of licenses	11.5%	6.8%	(4.7%)
Cost of services:			
Cardiac Safety	34.6%	29.8%	(4.8%)
Technology consulting and training	76.2%	74.2%	(2.0%)
Software maintenance	27.1%	25.1%	(2.0%)
Total cost of services	37.3%	31.6%	(5.7%)
Cost of site support	46.2%	49.4%	3.2%
Total costs of revenues	37.0%	33.2%	(3.8%)
Operating expenses:			
Selling and marketing	11.6%	8.6%	(3.0%)
General and administrative	10.2%	9.4%	(0.8%)
Research and development	6.8%	3.7%	(3.1%)

License revenues included an increase in revenue from the sale of perpetual licenses of \$3.2 million primarily due to the fact that the average license revenue for each of the perpetual licenses sold in 2004 generated license revenues substantially in excess of the average license revenue of the perpetual licenses sold in 2003 as a result of the mix of licenses sold and the number of users for each license. Additionally, there was an increase of approximately \$0.9 million in revenues for year ended December 31, 2004 versus the year ended December 31, 2003 for software licensed on a monthly and annual basis with new clients.

The increase in Cardiac Safety service revenues was primarily due to increased sales volume with both new and existing clients, including an increase in transactions performed, and a small increase in average revenue per transaction. Additionally, project assurance fees increased due to the fact that this fee was initiated during 2003 and that there was a greater percentage of active contracts that included this fee in 2004. The increase in sales volume in 2004 was partially attributed to an increase in comprehensive Thorough QTc studies.

Technology consulting and training revenues decreased primarily due to a reduction in consulting on clinical data management software products as there were several large consulting engagements in 2003 with nothing of a comparable size in 2004. The decrease in consulting on clinical data management software products was partially offset by an increase in configuration fees related to reporting capabilities for Cardiac Safety clients.

The increase in software maintenance service revenues was primarily due to new perpetual license sales during the year ended December 31, 2004.

Site support revenue increased primarily due to revenue from the rental of cardiac safety equipment, which our clients use to perform cardiac safety procedures. Additionally, equipment sales totaled \$2.7 million in 2004. There were no significant equipment sales in 2003.

The increase in the cost of Cardiac Safety services was primarily due to an increase in labor, depreciation and increased facilities and other costs associated with expanding capabilities to meet the growth in Cardiac Safety service revenues. Additionally, amortization expense related to internal use software costs was \$2.0 million for the year ended December 31, 2004 compared with \$1.4 million for the year ended December 31, 2003. See [Liquidity and Capital Resources] for additional information related to internal use software. The decrease in the cost of Cardiac Safety services as a percentage of Cardiac Safety service revenues was primarily due to the fact that some of the costs do not necessarily increase or decrease in direct relation with changes in revenue.

The decrease in the cost of technology consulting and training services, both in absolute terms and as a percentage of technology consulting and training service revenues, was due primarily to a reduction in third-party consulting costs partially offset by an increase in labor costs in the year ended December 31, 2004 versus the year ended December 31, 2003. The reduction in consulting costs resulted from the decrease in revenue as well as staffing additions which allowed for most of the work, especially in the latter part of 2004, to

be completed by employees.

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The increase in the cost of site support, both in absolute terms and as a percentage of site support revenues, was due primarily to an increase in rental and depreciation costs and supplies associated with cardiac safety rental equipment, cost of equipment sold in 2004 as there were no significant sales in 2003, and increased shipping costs and other costs associated with expanding capabilities to meet the growth in site support activities, including the addition of new dedicated site support facilities.

The increase in selling and marketing expenses was primarily due to increases in commissions that resulted from the increase in commissionable revenue, higher labor costs due to new hires, increased travel and entertainment and third-party consulting costs. These increased costs were partially offset by a reduction in bonuses due to higher targets in 2004 that were not fully achieved and savings resulting from not holding the annual users conference in 2004. The decrease in selling and marketing expenses as a percentage of total net revenues was primarily due to the increase in net revenues and the fact that selling and marketing expenses are discretionary in nature and can be increased or decreased as deemed necessary by management and do not necessarily increase or decrease with changes in revenues.

The increase in general and administrative expenses was due primarily to consultants assisting with internal control work required by the Sarbanes-Oxley Act as well as increased audit and internal control attestation fees of our independent registered public accountants, higher labor costs due to new hires, increased legal fees, non-income based taxes, depreciation, telecommunications, provision for uncollectible accounts, insurance costs and fees related to stock buybacks. These increases were partially offset by a planned reduction in public relations expenses and a reduction in incentive bonuses due to higher targets in 2004 that were not fully achieved. The decrease in general and administrative expenses as a percentage of total net revenues was primarily due to the increase in net revenues and the fact that general and administrative expenses do not necessarily increase or decrease with changes in revenues.

The decrease in research and development expenses, both in absolute terms and as a percentage of total net revenues, was due primarily to a reduction in labor costs resulting from a decrease in allocated administrative costs and the capitalization of expenditures related to internal use software development. Additionally, research and development expenses as a percentage of net revenues decreased due to the increase in net revenues and the fact that many of the research and development expenses do not necessarily increase or decrease with changes in revenues.

Other income, net, consisted primarily of interest income realized from our cash, cash equivalents, short-term investments and long-term investments as well as foreign exchange gains, net of interest expense related to capital lease obligations. The primary reason for the increase in 2004 was higher balances of cash, cash equivalents and short-term investments in 2004, foreign exchange gains and a decrease in interest expense related to capital leases in 2004.

Our effective tax rate was 37.9% and 40.8% for the years ended December 31, 2003 and 2004, respectively. The 2004 tax rate increased primarily due to increased income before taxes with relatively static offsets such as tax credits for research and development. As income increased, the impact of these tax offsets has decreased as a percentage of income before income taxes, and as a result, the effective tax rate has increased. Additionally, as a percentage of total company operating income, the operating income generated in the United States has increased which results in higher taxes as the blended federal, state and local tax rate is higher than the UK tax rate.

### **Liquidity and Capital Resources**

At December 31, 2005, we had \$18.4 million of cash and cash equivalents and \$36.6 million invested in short-term and long-term investments. We generally place our investments in money market funds, municipal securities, bonds of government sponsored agencies, certificates of deposit with fixed rates with maturities of less than one year, and A1P1 rated commercial bonds and paper.

For the year ended December 31, 2005, our operations provided cash of \$26.2 million compared to \$59.6 million during the year ended December 31, 2004. The change was primarily the result of lower net income and less income tax benefits related to stock options exercised during the year ended December 31, 2005 compared to the year ended December 31, 2004. The decrease in operating cash flow was also attributable to a decrease in deferred revenues in the year ended December 31, 2005 compared to an increase in the year ended





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December 31, 2004. In the 2005 period, franchise revenue exceeded franchise payments while in the 2004 period, franchise payments exceeded franchise revenue.

For the year ended December 31, 2005, our investing activities used cash of \$29.8 million compared to \$26.7 million during the year ended December 31, 2004. The change was primarily the result of net activity related to short-term investments and long-term investments, which used \$13.6 million of cash for the year ended December 31, 2005, compared to \$9.4 million for the year ended December 31, 2004. This increased use of cash was partially offset by a \$1.2 million decrease in cash used for purchases of property and equipment.

During the year ended December 31, 2005, we capitalized \$16.1 million of property and equipment compared to \$17.4 million capitalized during the year ended December 31, 2004. The decrease was primarily the result of software purchased in 2004 used in the development of the upgrade to EXPeRT® as discussed below.

Included in property and equipment is internal use software associated with the development of a data and communications management services software product (EXPeRT®) used in connection with our centralized core cardiac safety ECG services. We capitalize certain internal use software costs in accordance with Statement of Position 98-1. The amortization is charged to the cost of Cardiac Safety services beginning at the time the software is ready for its intended use. The initial development costs of EXPeRT® were for the basic functionality required for this product. Additional development costs of EXPeRT® were incurred to develop new functionalities and enhancements. We started a new internal use software project to allow for semi-automated processing of ECGs in the second quarter of 2003 and further enhancements were begun in October 2004. We also began capitalizing costs associated with an upgrade to EXPeRT® (EXPeRT® 2) beginning in the fourth quarter of 2003. In April 2005, we began developing enhancements to EXPeRT® which are necessary while EXPeRT® 2 continues to be developed.

In mid-August of 2004, we revised our estimated timing for the completion of EXPeRT® 2 to continue the development work through the fourth quarter of 2005, as opposed to the first quarter of 2005 as we previously had estimated. As this upgrade will replace many parts of the existing EXPeRT® product, we previously had accelerated the amortization of capitalized labor and consulting costs to fully amortize the associated costs of the existing EXPeRT® product by the end of the first quarter of 2005, which increased monthly amortization expense by \$76,000 beginning in the fourth quarter of 2003. Beginning in mid-August of 2004, we revised the remaining amortization period for previously capitalized labor and consulting costs to fully amortize the associated costs of the existing EXPeRT® product by the end of the fourth quarter of 2005, which decreased monthly amortization expense by \$76,000 beginning in mid-August 2004. At the beginning of April 2005, we extended the remaining life of the existing EXPeRT® product to co-exist with EXPeRT® 2 and extended the depreciation period through August 2006 which coincides with our standard useful life for internal use software of four years. This resulted in a decrease in monthly amortization expense of \$32,000 beginning in April 2005. At this time, we expect EXPeRT® 2 to go into production in September 2006.

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The following table presents the internal use software costs and related amortization as of December 31, 2005 (in thousands):

	<b>Amortization Period</b>	<b>Labor and Consulting</b>	<b>Related Direct Costs of Materials</b>	<b>Total Capitalized Costs</b>	<b>Monthly Amortization</b>	<b>Accumulated Amortization</b>
<b>EXPeRT®</b>						
Initial costs	August 2002-July 2006	\$ 2,618	\$ 1,413	\$ 4,031	\$ 55	\$ 3,639
Additional costs	April 2003-July 2006	1,003	50	1,053	13	949
Additional enhancements	October 2005-September 2007	463	□	463	21	30
<b>Semi-automated ECG processing software</b>						
Initial costs	February 2004-January 2008	449	361	810	17	390
Enhancements	October 2004-September 2008	380	□	380	8	120
Additional enhancements	April 2005-March 2009	376	□	376	8	72
Upgrade to EXPeRT®	September 2006-August 2010 (estimated)	5,436	1,139	6,575	□	□
<b>Total</b>		<b>\$ 10,725</b>	<b>\$ 2,963</b>	<b>\$ 13,688</b>	<b>\$ 122</b>	<b>\$ 5,200</b>

For the year ended December 31, 2005, our financing activities used cash of \$23.6 million compared to \$25.6 million for the year ended December 31, 2004. The change was primarily the result of a lower repurchase of common stock under our stock buy-back program in the 2005 period as compared to the 2004 period as well as lower net proceeds from the exercise of stock options in the 2005 period as compared to the 2004 period.

We have a line of credit arrangement with Wachovia Bank, National Association totaling \$3.0 million. For the year ended December 31, 2005, we had no borrowings under the line.

We have a commitment to purchase approximately \$5.0 million of private label cardiac safety equipment from a manufacturer over the twelve-month period ending in July 2006. This cardiac safety equipment is expected to be purchased in the normal course of business and thus does not represent a significant commitment above our expected purchases of ECG equipment during that period.

We expect that existing cash and cash equivalents, short-term investments, cash flows from operations and available borrowings under our line of credit will be sufficient to meet our foreseeable cash needs for at least the next year. However, there may be acquisition and other growth opportunities that require additional external financing and we may from time to time seek to obtain additional funds from the public or private issuances of equity or debt securities. There can be no assurance that any such acquisitions will occur or that such financings will be available or available on terms acceptable to us.

In the second quarter of 2005, the stock buy-back program that was originally announced in April 2004 and extended to 2.5 million shares in October 2004 was extended by an additional 10 million shares to a total of 12.5 million shares. The purchase of a majority of the shares authorized could require us to use a significant portion of our cash, cash equivalents and short-term investments and could also require us to seek additional external financing. The stock buy-back authorization allows us, but does not require us, to purchase the authorized shares. During the year ended December 31, 2005, we purchased 1,779,600 shares of our common stock at a cost of \$24.8 million.

The following table presents contractual obligations information as of December 31, 2005 (in thousands):

**Payments due by period**

<b>Contractual Obligations</b>	<b>Total</b>	<b>Less than 1 year</b>	<b>1-3 years</b>	<b>3-5 years</b>	<b>More than 5 years</b>
Capital lease obligations	\$ 204	\$ 163	\$ 41	\$ 0	\$ 0
Operating leases	15,725	5,284	6,550	2,779	1,112
<b>Total</b>	<b>\$ 15,929</b>	<b>\$ 5,447</b>	<b>\$ 6,591</b>	<b>\$ 2,779</b>	<b>\$ 1,112</b>

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### **Inflation**

We believe the effects of inflation and changing prices generally do not have a material adverse effect on our results of operations or financial condition.

### **Recent Pronouncements**

In December 2004, the Financial Accounting Standards Board (FASB) issued Statement of Financial Accounting Standards (SFAS) No. 123R, "Share-Based Payment." SFAS No. 123R is a revision of SFAS No. 123, "Accounting for Stock-Based Compensation." SFAS No. 123R establishes standards for the accounting for transactions in which an entity exchanges its equity instruments for goods or services. SFAS No. 123R requires companies to recognize in the statement of operations the grant-date fair value of stock options and other equity-based compensation issued to employees, but expresses no preference for a type of valuation model. In April 2005, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin No. 107 which provided additional guidance in implementing SFAS No. 123R without modifying the conclusions or requirements of SFAS No. 123R. In April 2005, the SEC also deferred the effective date of SFAS No. 123R for many registrants, including our company. The deferral now requires the adoption to be effective for our company no later than the first annual period beginning after June 15, 2005. We currently use the intrinsic value method to measure compensation expense for stock-based awards to our employees. Accordingly, we do not recognize any compensation expense related to stock option grants that we issue under our stock option plans. We will adopt SFAS No. 123R on January 1, 2006 under the modified prospective method of application. Under that method, we will recognize compensation costs for new grants of share-based awards, awards modified after the effective date, and the remaining portion of the fair value of the unvested awards at the adoption date. As described in Note 8 in the Notes to Consolidated Financial Statements, we accelerated the vesting of certain unvested options to minimize the recognition of compensation costs in 2006, 2007 and 2008 for previously granted unvested awards. We estimate that the adoption of SFAS No. 123R will result in the recognition of after-tax compensation costs for share-based awards equivalent to \$0.03 to \$0.04 per share in 2006 based upon unvested options at December 31, 2005 and planned 2006 option grants.

In December 2004, the FASB issued SFAS No. 153, "Exchanges of Nonmonetary Assets," which eliminates an exception in Accounting Principles Board (APB) Opinion No. 29, "Accounting for Nonmonetary Transactions," for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets that do not have commercial substance. SFAS No. 153 became effective for us for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. The adoption of SFAS No. 153 did not have any impact on our consolidated financial statements.

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections." SFAS No. 154 requires retroactive application of a voluntary change in accounting principle to prior period financial statements unless it is impracticable. SFAS No. 154 also requires that a change in method of depreciation, amortization, or depletion for long-lived, non-financial assets be accounted for as a change in accounting estimate that is affected by a change in accounting principle. SFAS No. 154 replaces APB Opinion 20, "Accounting Changes," and SFAS No. 3, "Reporting Accounting Changes in Interim Financial Statements." SFAS No. 154 will be effective for us for all accounting changes and any error corrections occurring after January 1, 2006.

### **Critical Accounting Policies**

In December 2001 and December 2003, the SEC issued disclosure guidance for "critical accounting policies." The SEC defines "critical accounting policies" as those that require application of management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods.

Our significant accounting policies are described in Note 1 in the Notes to Consolidated Financial Statements. Not all of these significant accounting policies require management to make difficult, subjective or complex judgments or estimates. However, the following policies could be deemed to be critical within the SEC definition.

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### *Revenue Recognition*

We recognize revenues primarily from three sources: license fees, services and site support. Our license revenues consist of license fees for perpetual license sales and monthly and annual license sales. Our services revenues consist of Cardiac Safety services, technology consulting and training services and software maintenance services. Our site support revenues consist of cardiac safety equipment rental and sales, supplies and freight.

We recognize software revenues in accordance with Statement of Position 97-2, "Software Revenue Recognition," as amended by Statement of Position 98-9, "Modification of SOP 97-2, Software Revenue Recognition, With Respect to Certain Transactions." Accordingly, we recognize up-front license fee revenues under the residual method when a formal agreement exists, delivery of the software and related documentation has occurred, collectability is probable and the license fee is fixed or determinable. We recognize monthly and annual license fee revenues over the term of the arrangement. Hosting service fees are recognized evenly over the term of service. Cardiac Safety services revenues consist of services that we provide on a fee for services basis and are recognized as services are performed. We recognize revenues from software maintenance contracts on a straight-line basis over the term of the maintenance contract, which is typically twelve months. We provide consulting and training services on a time and materials basis and recognize revenues as we perform the services. The rental of cardiac safety equipment is recognized over the rental period. Sales of equipment and supplies are recognized at the time of sale.

At the time of the transaction, management assesses whether the fee associated with our revenue transactions is fixed or determinable and whether or not collection is reasonably assured. The assessment of whether the fee is fixed or determinable is based upon the payment terms of the transaction. If a significant portion of a fee is due after our normal payment terms or upon implementation or client acceptance, the fee is accounted for as not being fixed or determinable. In these cases, revenue is recognized as the fees become due or after implementation or client acceptance has occurred.

Collectability is assessed based on a number of factors, including past transaction history with the client and the credit-worthiness of the client. If it is determined that collection of a fee is not reasonably assured, the fee is deferred and revenue is recognized at the time collection becomes reasonably assured, which is generally upon receipt of cash. Under a typical contract for Cardiac Safety services, clients pay us a portion of our fee for these services upon contract execution as an upfront deposit, some of which is typically nonrefundable upon contract termination. Revenues are then recognized under Cardiac Safety service contracts as the services are performed.

For arrangements with multiple deliverables where the fair value of each element is known, the revenue is allocated to each component based on the relative fair values of each element. For arrangements with multiple deliverables where the fair value of the delivered element is not known, revenue is allocated to each component of the arrangement using the residual method provided that the fair value of all undelivered elements is known. Fair values for undelivered elements are based primarily upon stated renewal rates for future products or services.

### *Accounting for Income Taxes*

As part of the process of preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves management having to estimate our current tax exposure together with assessing temporary differences resulting from the differing treatment of certain items for tax and accounting purposes. These differences result in deferred tax assets and liabilities, which are included in our consolidated balance sheets. Management must then assess the likelihood that our net deferred tax assets will be recovered from future taxable income, and, to the extent that management believes that recovery is not likely, a valuation allowance must be established. To the extent management establishes or increases a valuation allowance in a period, the consolidated statement of operations will reflect additional income tax expense.

Significant management judgment is required in determining our provision for income taxes, deferred taxes and any valuation allowance recorded against deferred tax assets. As of December 31, 2005, we had a valuation allowance of \$2.4 million related to the uncertain realization of certain deferred tax assets. See Note 5 in the Notes to Consolidated Financial Statements for more information.

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#### *Depreciation and Amortization of Long-lived Assets*

We compute depreciation on our property, plant and equipment on a straight-line basis over their estimated useful lives, which generally range from two to five years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the asset or the remaining lease term. System development costs are amortized on a straight-line basis over four years, or a shorter period if an upgrade replacement is expected to take place prior to the end of the four-year period. Changes in the estimated useful lives of property, plant and equipment could have a material effect on our results of operations.

The above listing is not intended to be a comprehensive list of all of our accounting policies. In many cases, the accounting treatment of a particular transaction is specifically dictated by generally accepted accounting principles, with no need for management's judgment in their application. There are also areas in which management's judgment in selecting any available alternatives would not produce a materially different result. See our audited Consolidated Financial Statements and Notes thereto, which begin on page F-1 of this Form 10-K, for a description of our accounting policies and other disclosures required by generally accepted accounting principles.

#### **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

Our primary financial market risks include fluctuations in interest rates and currency exchange rates.

##### **Interest Rate Risk**

We generally place our investments in money market funds, municipal securities, bonds of government sponsored agencies, certificates of deposit with fixed rates with maturities of less than one year, and A1P1 rated commercial bonds and paper. We actively manage our portfolio of cash equivalents, short-term investments and long-term investments, but in order to ensure liquidity, we will only invest in instruments with high credit quality where a secondary market exists. We have not held and do not hold any derivatives related to our interest rate exposure. Due to the average maturity and conservative nature of our investment portfolio, a sudden change in interest rates would not have a material effect on the value of the portfolio. Management estimates that had the average yield of our investments decreased by 100 basis points, our interest income for the year ended December 31, 2005 would have decreased by approximately \$0.6 million. This estimate assumes that the decrease occurred on the first day of 2005 and reduced the yield of each investment by 100 basis points. The impact on our future interest income of future changes in investment yields will depend largely on the gross amount of our cash, cash equivalents, short-term investments and long-term investments. See "Liquidity and Capital Resources" as part of "Management's Discussion and Analysis of Financial Condition and Results of Operations."

##### **Foreign Currency Risk**

We operate on a global basis from locations in the United States and the United Kingdom. All international net revenues and expenses are billed or incurred in either U.S. dollars or pounds sterling. As such, we face exposure to adverse movements in the exchange rate of the pound sterling. As the currency rate changes, translation of the income statement of our UK subsidiary from the local currency to U.S. dollars affects year-to-year comparability of operating results. We do not hedge translation risks because any cash flows from UK operations are generally reinvested in the UK.

Management estimates that a 10% change in the exchange rate of the pound sterling would have impacted the reported operating income for the year ended December 31, 2005 by less than \$0.3 million.

#### **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The information called for by this Item is set forth on Pages F-1 through F-24.

#### **ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE**

No disclosure required.



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**ITEM 9A. CONTROLS AND PROCEDURES**

Conclusions regarding disclosure controls and procedures

Our principal executive and principal financial officers, after evaluating the effectiveness of our disclosure controls and procedures (as defined in the Securities Exchange Act of 1934 Rule 13a-15(e) as of the end of the period covered by this report, have concluded that, based on the evaluation of these controls and procedures required by paragraph (b) of Exchange Act Rule 13a-15, our disclosure controls and procedures were effective to ensure that information we are required to disclose in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Management's annual report on internal control over financial reporting

See Management's Report on Internal Control Over Financial Reporting on page F-2.

Attestation report of the registered public accounting firm

See Report of Independent Registered Public Accounting Firm on page F-3.

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rule 13a-15 that occurred during our last fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**ITEM 9B. OTHER INFORMATION**

None.



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### **PART III**

#### **ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS OF THE REGISTRANT**

Information with respect to this item is set forth in our definitive Proxy Statement (the "Proxy Statement") to be filed with the SEC for our Annual Meeting of Stockholders to be held on April 25, 2006, under the headings "Election of Directors," "Section 16(a) Beneficial Ownership Reporting Compliance" and "Code of Ethics and Business Conduct," and is incorporated herein by reference. Information regarding our executive officers is included at the end of Part I of this Form 10-K.

#### **ITEM 11. EXECUTIVE COMPENSATION**

"Executive Compensation" in the Proxy Statement is incorporated by reference.

#### **ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS**

"Security Ownership of Certain Beneficial Owners and Management" and "Proposal to Amend 2003 Stock Option Plan-Existing Equity Compensation Plans" in the Proxy Statement are incorporated by reference.

#### **ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

"Certain Relationships and Related Party Transactions" in the Proxy Statement is incorporated by reference.

#### **ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

"Ratification of Independent Registered Public Accountants" in the Proxy Statement is incorporated by reference.

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## PART IV

### ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this Form 10-K:

1. The consolidated financial statements of eResearchTechnology, Inc. (the "Company") filed as a part of this Form 10-K are listed on the attached Index to Consolidated Financial Statements and Financial Schedule at F-1
2. The schedule to the consolidated financial statements of the Company filed as a part of this Form 10-K is listed in the attached Index to Consolidated Financial Statements and Financial Statement Schedule at F-1
3. Exhibits.
  - 3.1 Restated Certificate of Incorporation, as amended.(12)
  - 3.2 Bylaws.(1)
  - 3.3 Amendment to Bylaws.(2)
  - 3.4 Certificate of Merger between the Company and eRT Operating Company.(6)
  - 4.1 Form of Stock Certificate.(6)
  - 10.1 Registration Rights Agreement dated August 27, 1999.(3)
  - 10.2 Amendment to Management Consulting Agreement between Dr. Joel Morganroth and the Company effective January 1, 2003.(7)\*
  - 10.3 2003 Stock Option Plan.(8)\*
  - 10.7 1996 Stock Option Plan, as amended.(6)\*
  - 10.9 2005 Bonus Plan.(13)\*
  - 10.10 2005 Amended Bonus Plan.(15)\*
  - 10.11 2006 Bonus Plan.\*
  - 10.23 Sublease Agreement between the Company and Raytheon Engineers & Constructors, Inc.(2)
  - 10.25 Amendment to the Sublease Agreement between the Company and 17th Ludlow Property, L.L.C.(9)
  - 10.26 Amendment to the Sublease Agreement between the Company and 17th Ludlow Property, L.L.C.(11)
  - 10.30 Promissory Note to Wachovia Bank, National Association.(14)
  - 10.31 Loan Agreement with Wachovia Bank, National Association.(11)
  - 10.38 Management Employment Agreement effective January 1, 2004 between Joseph Esposito and the Company.(10)\*

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- 10.39 Amendment to Management Employment Agreement effective August 16, 2004 between Joseph Esposito and the Company.(12)\*
- 10.40 Management Employment Agreement effective February 7, 2006 between Joseph Esposito and the Company.\*
- 10.41 Amendment to Management Employment Agreement effective August 16, 2004 between Dr. Joel Morganroth and the Company.(12)\*
- 10.42 Amendment to Management Consulting Agreement effective January 1, 2005 between Dr. Joel Morganroth and the Company.(13)\*
- 10.43 Management Employment Agreement effective August 20, 2004 between Bruce Johnson and the Company.(12)\*
- 10.44 Management Employment Agreement effective August 20, 2004 between Dr. Jeffrey Litwin and the Company.(12)\*
- 10.45 Management Employment Agreement effective August 20, 2004 between Vincent Renz and the Company.(12)\*
- 10.46 Management Employment Agreement effective August 20, 2004 between Scott Grisanti and the Company.(12)\*
- 10.47 Amendment to Management Consulting Agreement effective January 1, 2006 between Dr. Joel Morganroth and the Company.\*
- 10.52 Lease Agreement dated August 18, 2000 between Advance/GLD 2 L.L.C. and the Company.(4)
- 10.54 Lease Agreement dated September 28, 2004 between Royal and Sun Alliance Insurance PLC and the Company's subsidiary, eResearchTechnology Limited.(13)
- 10.56 Management Employment Agreement effective May 21, 2001 between Dr. Joel Morganroth and the Company.(5)\*
- 10.57 Management Consulting Agreement effective May 21, 2001 between Dr. Joel Morganroth and the Company.(5)\*
- 10.59 Attornment Agreement between 17th Ludlow Property, L.L.C. and the Company.(6)
- 21.1 Subsidiaries of the Registrant.
- 23.1 Consent of KPMG LLP.
- 31.1 Certification of Chief Executive Officer.
- 31.2 Certification of Chief Financial Officer.
- 32.1 Statement of Chief Executive Officer Pursuant to Section 1350 of Title 18 of the United States Code.
- 32.2 Statement of Chief Financial Officer Pursuant to Section 1350 of Title 18 of the United States Code.



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- \* Management contract or compensatory plan or arrangement.
- (1) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Registration Statement on Form S-1, File No. 333-17001, declared effective by the Securities and Exchange Commission on February 3, 1997.
  - (2) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-K on March 31, 1999.
  - (3) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 8-K on September 9, 1999.
  - (4) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-Q on November 13, 2000.
  - (5) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-Q on August 10, 2001.
  - (6) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-K on March 12, 2002.
  - (7) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-K on March 14, 2003.
  - (8) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-Q on August 7, 2003.
  - (9) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-Q on November 7, 2003.
  - (10) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-K on March 15, 2004.
  - (11) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-Q on May 3, 2004.
  - (12) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-Q on November 4, 2004.
  - (13) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-K on March 11, 2005.
  - (14) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-Q on August 4, 2005.
  - (15) Incorporated by reference to the exhibit with the same number, filed in connection with the Company's Form 10-Q on November 3, 2005.

[Back to Contents](#)**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on this 10th day of March, 2006.

**eResearchTechnology, Inc.**

By: Joseph A. Esposito

\_\_\_\_\_  
 Joseph A. Esposito  
*President and Chief Executive Officer, Director*

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
_____ Joseph A. Esposito	President and Chief Executive Officer, Director (Principal executive officer)	March 10, 2006
_____ Joseph A. Esposito		
_____ Joel Morganroth, MD	Chairman of the Board of Directors	March 10, 2006
_____ Joel Morganroth, MD		
_____ Bruce Johnson	Executive Vice President and Chief Financial Officer (Principal financial and accounting officer)	March 10, 2006
_____ Bruce Johnson		
_____ Sheldon M. Bonovitz	Director	March 10, 2006