

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

[Back to Contents](#)

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the Fiscal Year ended December 31, 2004
or

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

For the transition period from _____ to _____

Commission File No. 0-29100

eResearchTechnology, Inc.

(Exact name of issuer as specified in its charter)

Delaware
(State of incorporation)

22-3264604

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

30 South 17th Street Philadelphia, PA 19103

(Address of Principal Executive Offices)

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

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

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, \$.01 par value

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

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

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

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

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

DOCUMENTS INCORPORATED BY REFERENCE

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

[Back to Contents](#)

TABLE OF CONTENTS

Item Number

<u>PART I</u>	
<u>1</u>	<u>Business</u> <u>3</u>
	<u>General</u> <u>3</u>
	<u>Product and Service Offerings</u> <u>3</u>
	<u>Technology</u> <u>6</u>
	<u>Research and Development</u> <u>7</u>
	<u>Our Clients</u> <u>7</u>
	<u>Sales and Marketing</u> <u>7</u>
	<u>Partnerships</u> <u>7</u>
	<u>Competition</u> <u>8</u>
	<u>Government Regulation</u> <u>8</u>
	<u>Potential Liability and Insurance</u> <u>9</u>
	<u>Intellectual Property</u> <u>9</u>
	<u>Employees</u> <u>10</u>
	<u>Website</u> <u>10</u>
<u>2</u>	<u>Properties</u> <u>10</u>
<u>3</u>	<u>Legal Proceedings</u> <u>10</u>
<u>4</u>	<u>Submission of Matters to a Vote of Security Holders</u> <u>11</u>
<u>Special</u>	<u>Executive Officers of Registrant</u> <u>11</u>
<u>PART II</u>	
<u>5</u>	<u>Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u> <u>13</u>
<u>6</u>	<u>Selected Financial Data</u> <u>14</u>
<u>7</u>	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> <u>15</u>
	<u>Cautionary Statement for Forward-Looking Information</u> <u>15</u>
	<u>Overview</u> <u>15</u>
	<u>Results of Operations</u> <u>16</u>
	<u>Executive Overview</u> <u>16</u>
	<u>Year Ended December 31, 2004 Compared to the Year Ended December 31, 2003</u> <u>18</u>
	<u>Year Ended December 31, 2003 Compared to the Year Ended December 31, 2002</u> <u>21</u>
	<u>Revised Outlook for Quarter Ending March 31, 2005</u> <u>23</u>
	<u>Liquidity and Capital Resources</u> <u>24</u>
	<u>Inflation</u> <u>25</u>
	<u>Recent Pronouncements</u> <u>25</u>
	<u>Critical Accounting Policies</u> <u>26</u>
	<u>Risks Related to our Business</u> <u>27</u>
<u>7A</u>	<u>Quantitative and Qualitative Disclosures About Market Risk</u> <u>34</u>
	<u>Interest Rate Risk</u> <u>34</u>
	<u>Foreign Currency Risk</u> <u>35</u>
<u>8</u>	<u>Financial Statements and Supplementary Data</u> <u>35</u>
<u>9</u>	<u>Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u> <u>35</u>
<u>9A</u>	<u>Controls and Procedures</u> <u>35</u>
<u>9B</u>	<u>Other Information</u> <u>35</u>
<u>PART III</u>	
<u>10</u>	<u>Directors and Executive Officers of the Registrant</u> <u>36</u>
<u>11</u>	<u>Executive Compensation</u> <u>36</u>

<u>12</u>	<u>Security Ownership of Certain Beneficial Owners and Management</u>	<u>36</u>
<u>13</u>	<u>Certain Relationships and Related Transactions</u>	<u>36</u>
<u>14</u>	<u>Principal Accountant Fees and Services</u>	<u>36</u>
	<u>PART IV</u>	
<u>15</u>	<u>Exhibits and Financial Statement Schedules</u>	<u>37</u>
	<u>Signatures</u>	<u>40</u>
	<u>Index to Consolidated Financial Statements and Schedule</u>	<u>F-1</u>

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

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

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

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

Product and Service Offerings**Product/Services****Description**

EXPeRT®

Diagnostic tests are employed in clinical trials to measure the effect of the product on certain body organs and systems in order to determine the product's safety. Cardiac Safety testing is one example of these diagnostic tests. Cardiac Safety services are provided by us through our regulatory compliant (Title 21 CFR, Part 11) EXPeRT® Cardiac Safety Intelligent Data Management System. EXPeRT® provides for workflow enabled cardiac safety data collection, interpretation and distribution of electrocardiographic (ECG) data and images as well as for analysis and cardiologist interpretation of ECGs performed on research subjects in connection with our clients' clinical trials. The ECG provides an electronic map of the heart's rhythm and structure, and typically is performed in most clinical trials. This service permits assessment of the safety of therapies by documenting the occurrence of cardiac electrical change.

EXPeRT® is designed specifically to address the emerging global regulatory guidance and technical standards for digital ECG processing to include digital collection, waveform measurements and annotations, review and output to the regulatory standard file format. EXPeRT® also provides for paper-based ECG processing as well as for paper ECGs to be scanned into a digital format and then to be annotated and submitted to the cardiologist for interpretation. EXPeRT® includes the ability for ECGs to be

[Back to Contents](#)

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

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

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

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

- Digital ECG Services. Digital ECG Services allow the investigator to transmit, via modem, 12-lead ECG data directly to us for interpretation and rapid return of results to the investigator and the sponsor. ECGs are measured by our cardiac safety specialists utilizing an on screen, high-resolution caliper placement system, and are then interpreted by a cardiologist. We also offer cardiac safety specialist and cardiologist adjudication of software algorithm placed measurements where appropriate and as desired by our clients.
- Continuous Digital 12-lead ECG Recording. Continuous digital 12-lead ECG signals are recorded for up to 24 hours onto compact flash memory cards and submitted to us. From these recordings, 12-lead ECGs can be evaluated at specific time points. These ECGs are measured by a cardiac safety specialist and then interpreted by a cardiologist. Continuous digital 12-lead ECG recordings can also be used for studies assessing the incidence of arrhythmias, cardiac ischemia and/or heart rate variability findings.
- Holter Recording. Holter recording is a 24- or 48-hour continuous ECG recording of the heart's rhythm on a cassette tape that is reviewed by a cardiac safety specialist and then by a cardiologist. Holter data reported by us is provided for studies assessing the incidence of arrhythmias, cardiac ischemia and/or heart rate variability.
- Paper ECG Services. Paper ECGs are measured by our cardiac safety specialists utilizing a high-resolution digitizing system, and are then interpreted by a cardiologist. Alternatively, paper ECGs may be scanned to a digital format, where appropriate.
- FDA XML ECG Service. FDA XML (Extensible Markup Language) ECG service provides our clients with electronic versions of each ECG processed by EXPeRT®. The ECGs processed by EXPeRT® are

[Back to Contents](#)

rendered in a format compliant with the FDA's emerging XML standard for digital ECGs.

- The Digital ECG Community, a hosted solution based on the eResearch Community application, delivers near real time Cardiac Safety feedback at the program, trial, center and patient level, along with related metrics, such as trial enrollment, as well as the ability to organize and publish a variety of study-specific information and the ability to link data points in reports direct to digital ECG waveforms.

eResearch Community (eRC)

A central command and control portal that provides real-time information related to monitoring clinical (eRC) trial activities, data quality and safety. The eRC technology is specifically designed to optimize clinical research assets — people, processes and information — by providing the participants in clinical research access to real time analysis and decision support capabilities along with a wide array of value added services and content designed to optimize the clinical research process. eRC includes our eResearch Dashboard module, which allows participants in the clinical trial to follow the progress and conduct of a study based on frequently updated data. This product allows the participant to analyze data and generate reports in a broad variety of formats that permit early strategic intervention in the clinical trial. eRC also includes a web-based training environment, eHealth Education, that allows clinical research professionals to learn about technology developments, new products, clinical protocols, and other educational matters.

eData Entry (eDE)

A comprehensive electronic data capture (EDC) system comprised of technology and consulting services formulated to deliver rapid time to benefit for electronic trial initiatives. Among the EDC offerings is a hosted turnkey electronic clinical trial environment that requires no capital investment or significant business process redesign. The program includes comprehensive system implementation, study support, and site support services. Sponsor, CRO and investigative site access is delivered through our eRC, a clinical research portal that serves as a focal point for trial stakeholders accessing our EDC technology, eResearch Dashboard key trial metrics, and related trial information.

eResearch Network (eResNet)

An integrated end-to-end clinical research solution that allows a sponsor or CRO to establish an infrastructure that connects multiple participants in the clinical trial process and that can be used repeatedly for future clinical trials. As an established infrastructure, an eResNet will allow a sponsor or CRO to improve the efficiency and speed of the clinical trial by automating the process for conducting each new clinical trial. The eResNet includes the following modules:

eData Management (eDM)

A clinical data management application for collecting, cleaning and managing clinical trial data. Clients use this technology to analyze data, resolve incomplete or erroneous data entries and support early locking of the database for a particular trial. This product easily integrates with a wide variety of third-party software applications in areas such as data analysis.

eSafety Net

An adverse event management system. This application facilitates compliance by sponsors, CROs and investigators with regulatory reporting requirements regarding adverse events and with the sponsor's or CRO's own internal requirements for safety data analysis.

[Back to Contents](#)

eStudy Conduct[] A clinical trial management technology that can be used to set up clinical trials, establish standards, track study activities, plan resources, distribute supplies, manage the financial aspects of a trial and electronically view clinical trial data.

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

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

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

Technology

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

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

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

[Back to Contents](#)

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

Research and Development

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

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

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

Our Clients

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

Sales and Marketing

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

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

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

Partnerships

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

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

[Back to Contents](#)

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

Competition

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

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

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

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

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

Government Regulation

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

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

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

[Back to Contents](#)

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

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

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

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

Potential Liability and Insurance

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

Intellectual Property

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

[Back to Contents](#)

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

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

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

Employees

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

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

Website

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

ITEM 2. PROPERTIES

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

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

ITEM 3. LEGAL PROCEEDINGS

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

[Back to Contents](#)

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

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

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

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

SPECIAL ITEM. EXECUTIVE OFFICERS OF REGISTRANT

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

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

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

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

[Back to Contents](#)

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

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

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

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

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

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

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

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

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

[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 29, 2003, we effected a 2-for-1 split of our common stock and on November 26, 2003 and May 27, 2004, we effected 3-for-2 splits of our common stock. Market prices in the following table have been restated to reflect these splits of our common stock as if the stock splits had occurred as of December 31, 2002.

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

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

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

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

ISSUER PURCHASES OF EQUITY SECURITIES

Period	(a) Total Number of Shares Purchased	(b) Average Price Paid per Share	(c) Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number of Shares that May Yet Be Purchased Under the Plans or Programs
October 1 through October 31	575,000	\$ 11.15	575,000	1,625,000
November 1 through November 30	930,000	\$ 13.09	930,000	695,000
December 1 through December 31	200,000	\$ 15.12	200,000	495,000
Total for the quarter	1,705,000	\$ 12.67	1,705,000	

[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,				
	2000	2001	2002	2003	2004
Net revenues:					
Licenses	\$ 5,189	\$ 1,372	\$ 2,119	\$ 5,738	\$ 9,803
Services	20,581	23,355	31,344	46,791	76,340
Site support	2,297	3,270	8,063	14,313	23,250
Total net revenues	28,067	27,997	41,526	66,842	109,393
Costs of revenues:					
Cost of licenses	721	576	896	658	664
Cost of services	12,350	11,046	12,816	17,473	24,124
Cost of site support	946	1,342	4,301	6,610	11,486
Total costs of revenues	14,017	12,964	18,013	24,741	36,274
Gross margin	14,050	15,033	23,513	42,101	73,119
Operating expenses:					
Selling and marketing	4,754	5,427	6,719	7,763	9,391
General and administrative	6,593	5,188	5,695	6,804	10,103
Research and development	4,840	4,865	4,256	4,564	4,090
Write-off of registration costs	782	□	□	□	□
Total operating expenses	16,969	15,480	16,670	19,131	23,584
Operating income (loss)	(2,919)	(447)	6,843	22,970	49,535
Other income, net	1,770	941	868	310	690
Investment impairment charge	□	(5,686)	□	□	□
Gain on sale of domestic CRO operation	2,114	1,422	35	□	□
Income (loss) before income taxes and minority interest	965	(3,770)	7,746	23,280	50,225
Income tax provision (benefit)	322	(112)	1,596	8,817	20,501
Minority interest dividend(1)	523	116	□	□	□
Net income (loss)	\$ 120	\$ (3,774)	\$ 6,150	\$ 14,463	\$ 29,724
Basic net income (loss) per share	\$ 0.00	\$ (0.08)	\$ 0.13	\$ 0.29	\$ 0.58
Diluted net income (loss) per share	\$ 0.00	\$ (0.08)	\$ 0.12	\$ 0.27	\$ 0.54

Consolidated Balance Sheet Data (in thousands)**December 31,**

Edgar Filing: ERESEARCHTECHNOLOGY INC /DE/ - Form 10-K

	<u>2000</u>	<u>2001</u>	<u>2002</u>	<u>2003</u>	<u>2004</u>
Cash, cash equivalents and short-term investments	\$ 27,657	\$ 18,430	\$ 26,750	\$ 51,922	\$ 68,748
Working capital	30,689	20,689	24,693	45,777	57,913
Total assets	53,964	41,000	53,392	91,978	116,525
Total stockholders' equity	34,170	32,792	40,580	69,259	86,854

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

[Back to Contents](#)

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 includes a number of forward-looking statements, including, but not limited to, expectations for 2005 and beyond regarding performance under partnership arrangements, amortization of expense for software development costs and expected trends in revenues and expenses. While such forward-looking statements reflect our current views with respect to future events and financial performance, you should not place undue reliance on these forward-looking statements, which apply only as of the date of this Form 10-K. We use words such as anticipate, believe, expect, intend and similar expressions to identify forward-looking statements. 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 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 this item under the caption "Risks Related to our Business."

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 and interpretation and new drug, biologic and device application submission. We offer Cardiac Safety services, which are utilized by clinical trial sponsors and Clinical Research Organizations (CROs) during the conduct of clinical trials, including comprehensive Thorough QTc studies. 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. Changes in the allocation of the sales price among the deliverable elements might impact the timing of revenue recognition, but would not change the total revenue recognized on the contract.

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

[Back to Contents](#)

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, 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 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 and the UK. Our international net revenues represented approximately 24%, 22% and 14% of total net revenues for the years ended December 31, 2002, 2003 and 2004, respectively. Revenues are recognized where the work is performed and not based upon the location of the client or the study.

Results of Operations

Executive Overview

2004 marked a year of continued growth and evolution. Revenue, net income and operating cash flow for the year all increased substantially over 2003, despite continuing investment in product line extension for semi-automated processing, increased sales and marketing expenditures, the impact of an increased tax rate and increased costs associated with expanding capabilities to meet the growth in Cardiac Safety service revenues and site support revenues.

In March 2004, we were issued a United States 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 patent includes more than 50 claims directed to various features of our EXPeRT[®] workflow enabled data handling technology.

During 2004, we purchased over 2 million shares of our stock for approximately \$28.2 million under a stock buy-back program authorized by our Board of Directors, and we were still able to increase cash significantly from the end of 2003.

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. For example, in the June 2004 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. We have historically been a leader in the industry in manual processing and we now also provide semi-automated processing with the same service level commitments to our customers as we have with our 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.

[Back to Contents](#)

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

	Year Ended December 31,		
	2002	2003	2004
Net revenues:			
Licenses	5.1%	8.6%	9.0%
Services	75.5	70.0	69.8
Site support	19.4	21.4	21.2
Total net revenues	100.0	100.0	100.0
Costs of revenues:			
Cost of licenses	2.2	1.0	0.6
Cost of services	30.9	26.1	22.1
Cost of site support	10.3	9.9	10.5
Total costs of revenues	43.4	37.0	33.2
Gross margin	56.6	63.0	66.8
Operating expenses:			
Selling and marketing	16.2	11.6	8.6
General and administrative	13.7	10.2	9.2
Research and development	10.2	6.8	3.7
Total operating expenses	40.1	28.6	21.5
Operating income	16.5	34.4	45.3
Other income, net	2.2	0.4	0.6
Income before income taxes	18.7	34.8	45.9
Income tax provision	3.9	13.2	18.7
Net income	14.8%	21.6%	27.2%

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

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

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

Operating expenses:				
Selling and marketing	7,763	9,391	1,628	21.0%
General and administrative	6,804	10,103	3,299	48.5%
Research and development	4,564	4,090	(474)	(10.4%)
	<u> </u>	<u> </u>	<u> </u>	
Total operating expenses	19,131	23,584	4,453	23.3%
	<u> </u>	<u> </u>	<u> </u>	
Operating income	22,970	49,535	26,565	115.7%
Other income, net	310	690	380	122.6%
	<u> </u>	<u> </u>	<u> </u>	
Income before income taxes	23,280	50,225	26,945	115.7%
Income tax provision	8,817	20,501	11,684	132.5%
	<u> </u>	<u> </u>	<u> </u>	
Net income	<u>\$ 14,463</u>	<u>\$ 29,724</u>	<u>\$ 15,261</u>	105.5%

[Back to Contents](#)

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

	Year Ended December 31,		Increase (Decrease)
	2003	2004	
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%	9.2%	(1.0%)
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. 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. In addition, if drug sponsors shift towards semi-automated processing using software algorithm placed measurements in place of our manual high-resolution caliper placement system, more competitors may join our market, thus reducing pricing and our market share. The effect of such action may reduce our average revenue per transaction.

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. We have seen increased interest from clients in purchasing equipment during 2004 which could indicate additional sales might occur in future periods.

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.

[Back to Contents](#)

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.

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, 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 foreign exchange gains, 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 and short-term investments, 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 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. We expect this trend to continue in 2005. Based on our preliminary assessment, as well as our review of other factors affecting our effective tax rate, we believe our effective tax rate will increase to approximately 41.0% in 2005. 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.

[Back to Contents](#)**Year Ended December 31, 2003 Compared to the Year Ended December 31, 2002**

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

	Year Ended December 31,			
	2002	2003		
Licenses				
Net revenues	\$ 2,119	\$ 5,738	\$ 3,619	170.8%
Costs of revenues	896	658	(238)	(26.6%)
Gross margin	\$ 1,223	\$ 5,080	\$ 3,857	315.4%
Services:				
Cardiac Safety				
Net revenues	\$ 24,999	\$ 38,986	\$ 13,987	56.0%
Costs of revenues	9,935	13,490	3,555	35.8%
Gross margin	\$ 15,064	\$ 25,496	\$ 10,432	69.3%
Technology consulting and training				
Net revenues	\$ 2,464	\$ 3,800	\$ 1,336	54.2%
Costs of revenues	1,621	2,897	1,276	78.7%
Gross margin	\$ 843	\$ 903	\$ 60	7.1%
Software maintenance				
Net revenues	\$ 3,881	\$ 4,005	\$ 124	3.2%
Costs of revenues	1,260	1,086	(174)	(13.8%)
Gross margin	\$ 2,621	\$ 2,919	\$ 298	11.4%
Total services				
Net revenues	\$ 31,344	\$ 46,791	\$ 15,447	49.3%
Costs of revenues	12,816	17,473	4,657	36.3%
Gross margin	\$ 18,528	\$ 29,318	\$ 10,790	58.2%
Site support:				
Net revenues	\$ 8,063	\$ 14,313	\$ 6,250	77.5%
Costs of revenues	4,301	6,610	2,309	53.7%
Gross margin	\$ 3,762	\$ 7,703	\$ 3,941	104.8%
Total				
Net revenues	\$ 41,526	\$ 66,842	\$ 25,316	61.0%
Costs of revenues	18,013	24,741	6,728	37.4%
Gross margin	23,513	42,101	18,588	79.1%

Operating expenses:				
Selling and marketing	6,719	7,763	1,044	15.5%
General and administrative	5,695	6,804	1,109	19.5%
Research and development	4,256	4,564	308	7.2%
	<u> </u>	<u> </u>	<u> </u>	
Total operating expenses	16,670	19,131	2,461	14.8%
	<u> </u>	<u> </u>	<u> </u>	
Operating income	6,843	22,970	16,127	235.7%
Other income, net	903	310	(593)	(65.7%)
	<u> </u>	<u> </u>	<u> </u>	
Income before income taxes	7,746	23,280	15,534	200.5%
Income tax provision	1,596	8,817	7,221	452.4%
	<u> </u>	<u> </u>	<u> </u>	
Net income	\$ 6,150	\$ 14,463	\$ 8,313	135.2%
	<u> </u>	<u> </u>	<u> </u>	

[Back to Contents](#)

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

	Year Ended December 31,		Increase (Decrease)
	2002	2003	
Cost of licenses	42.3%	11.5%	(30.8%)
Cost of services:			
Cardiac Safety	44.5%	34.6%	(9.9%)
Technology consulting and training	65.8%	76.2%	10.4%
Software maintenance	32.5%	27.1%	(5.4%)
Total cost of services	44.6%	37.3%	(7.3%)
Cost of site support	32.5%	46.2%	13.7%
Total costs of revenues	43.4%	37.0%	(6.4%)
Operating expenses:			
Selling and marketing	16.2%	11.6%	(4.6%)
General and administrative	13.7%	10.2%	(3.5%)
Research and development	10.2%	6.8%	(3.4%)

The increase in license revenues was primarily due to an increase of \$1.7 million in software licensed on a monthly and annual basis with new clients and the sale of eleven perpetual licenses during the year ended December 31, 2003 versus five perpetual licenses during the year ended December 31, 2002, which resulted in an increase in revenues of \$1.9 million.

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. Additionally, the average revenue per transaction increased with a shift to digital ECG processing and the implementation of project assurance fees.

The increase in technology consulting and training service revenues was primarily due to increased consulting activities for new clients as well as increases in implementation fees from new licenses. Additionally, we initiated sales of validation and standard operating procedure guides in 2003.

The increase in software maintenance service revenues was primarily due to new perpetual license sales during the year ended December 31, 2003.

The increase in site support revenues was primarily due to increased volume which resulted in an increase in the rental of cardiac safety equipment, which our clients use to perform cardiac safety procedures. Additionally, equipment rental associated with the franchises that began in the third quarter of 2003 increased site support revenues.

The decrease in the cost of licenses, both in absolute terms and as a percentage of license revenues, was primarily due to a decrease in ASP hosting fees associated with a change in ASP hosting providers at the beginning of 2003, including a termination fee paid to the previous ASP hosting provider in 2002. Additionally, the cost of licenses as a percentage of license revenues decreased due to the increase in revenue from perpetual licenses that have very little incremental cost of sales.

The increase in the cost of Cardiac Safety services was primarily due to an increase in labor, depreciation, facilities and other costs associated with expanding capabilities to meet the growth in Cardiac Safety service revenues. We also began amortization of our internal use software costs during the third quarter of 2002. Additional internal use software costs were capitalized throughout the remainder of 2002 and through the first quarter of 2003. We began amortizing the additional capitalized costs in the second quarter of 2003. We accelerated the amortization of certain internal use software costs due to an upgrade replacement that was scheduled to take place in 2005. The majority of these costs were to be amortized through August 2006. The increase in monthly amortization costs due to the acceleration was \$76,000 commencing in the fourth quarter of 2003 and was to continue through March 2005. Amortization expense related to internal use software costs was

\$1.4 million for the year ended December 31, 2003 and \$0.4 million for the year ended December 31, 2002. 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 are fixed in nature.

[Back to Contents](#)

The increase 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 increased third party consulting and labor costs associated with the increase in technology consulting and training service revenues as well as increased bonuses due to improved performance during the year ended December 31, 2003 as compared to the year ended December 31, 2002.

The decrease in the cost of software maintenance services, both in absolute terms and as a percentage of software maintenance service revenues, was due primarily to a reduction in labor, office rent, depreciation and other costs during the year ended December 31, 2003 as a result of a proportional decrease in allocated costs relative to other cost centers.

The increase in the cost of site support, both in absolute terms and as a percentage of site support revenues, was primarily due to an increase in labor, rental and depreciation costs associated with cardiac safety rental equipment, and other costs associated with expanding capabilities to meet the growth in site support revenues.

The increase in selling and marketing expenses was due primarily to increases in commissions that resulted from the increase in commissionable revenue, bonuses due to improved performance during 2003 and labor costs. These items were partially offset by planned reductions in advertising expense during the year ended December 31, 2003. 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 many 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 revenue.

The increase in general and administrative expenses was due primarily to an increase in insurance, public relations, bonuses and payroll taxes related to stock option exercises during the year ended December 31, 2003. 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 many of the general and administrative expenses are fixed in nature.

The increase in research and development expenses was primarily due to an increase in labor costs, third-party consulting and bonuses during the year ended December 31, 2003. The decrease in research and development expenses as a percentage of total net revenues was primarily due to the increase in net revenues and the fact that many of the research and development expenses are fixed in nature.

Other income, net, consisted primarily of interest income realized from our cash, cash equivalents and short-term investments, net of interest expense related to capital lease obligations. We recorded a net realized gain of \$0.4 million from the sale of our shares of Digital Angel Corporation (DAC) (formerly known as Medical Advisory Systems, Inc.) during 2002. Additionally, during 2002, a gain of \$35,000 was recognized on the sale of the domestic clinical research operation (CRO) to SCP Communications, Inc. and \$47,000 of interest income was recorded on the escrow accounts related to this sale. In addition to the gain on the sale of the DAC shares, the gain on sale of the domestic CRO and the interest income earned on the escrow accounts, all of which were realized during 2002, the decrease in other income, net was also due to lower interest rates during the year ended December 31, 2003.

Our effective tax rate was 20.6% and 37.9% for the years ended December 31, 2002 and 2003, respectively. The 2003 increase in the tax rate was primarily due to the non-recurring reversal of the valuation allowance related to certain state net operating loss carryforwards that was recorded in 2002, the increase in the state tax effective rate and increased income before taxes with relatively static offsets such as tax credits for research and development of \$0.6 million. As income increased, the impact of these tax offsets has decreased as a percentage of income before income taxes. Thus, the effective tax rate increased. The 2002 tax rate was primarily impacted by the reversal of \$1.1 million of valuation allowances related to certain state net operating loss carryforwards.

Revised Outlook for Quarter Ending March 31, 2005

On March 10, 2005, we issued a press release updating our outlook for the quarter ending March 31, 2005. We anticipate that our revenues will be 12-18% below the low end of our previous guidance range and that, due to the relatively fixed nature of the operating expenses, the percentage impact on earnings per share will be greater than on revenue. There continues to be significant uncertainty in the clinical research and drug development

industry, due in part to evolving regulatory guidance. See [Risks Related to Our Business](#)

[Back to Contents](#)

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 could increase competition and reduce our market share. We believe that this uncertainty continues to delay new contract signings and extend the time for initiation of new studies. Although we believe that further clarification of this regulatory guidance will be provided in the second quarter of 2005 and that the continued uncertainty that we believe has temporarily impacted our industry will be alleviated, our results of operations may continue to be adversely affected if this clarification is delayed or does not adequately address the uncertainty in the industry.

Liquidity and Capital Resources

For the year ended December 31, 2004, our operations provided cash of \$59.3 million compared to \$30.6 million during the year ended December 31, 2003. The change was primarily the result of improved operating income, a smaller increase in accounts receivable due to the impact of franchise study activity which is largely prepaid and larger income tax benefits related to stock options recognized during the year ended December 31, 2004 compared to the year ended December 31, 2003. This change was partially offset by an increase in prepaid expenses and other, accounts payable and accrued expenses.

For the year ended December 31, 2004, our investing activities used cash of \$26.4 million compared to \$13.1 million during the year ended December 31, 2003. The change was primarily the result of the net purchases of short-term investments, which totaled \$9.4 million for the year ended December 31, 2004, compared to \$4.3 million for the year ended December 31, 2003.

During the year ended December 31, 2004, we capitalized \$17.0 million of property and equipment compared to \$8.9 million capitalized in 2003. The increase was primarily the result of increased purchases of cardiac safety rental equipment and related computer equipment during the current year. This equipment was used to support the increased site support activity and contributed significantly to the increase in revenues in 2004.

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 electrocardiographic 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® beginning in the fourth quarter of 2003.

In mid-August of 2004, we revised our estimated timing for the completion of the upgrade to EXPeRT®. We now expect to continue the development of the upgrade to EXPeRT® through the fourth quarter of 2005 as opposed to the first quarter as we previously had estimated. At this time, we expect to begin amortizing these costs during 2006. As this upgrade will replace many parts of the existing EXPeRT® product we previously had accelerated the amortization of previously 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 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. The start date is estimated and could be extended, which would result in a further decrease in the monthly amortization.

[Back to Contents](#)

The following table presents the internal use software costs and related amortization as of December 31, 2004 (in thousands):

	<u>Amortization Start Date</u>	<u>Labor and Consulting</u>	<u>Related Direct Costs of Materials</u>	<u>Total Capitalized Costs</u>	<u>Monthly Amortization</u>	<u>Accumulated Amortization</u>
EXPeRT®						
Initial costs	August 2002	\$ 2,618	\$ 1,413	\$ 4,031	\$ 76	\$ 2,916
Additional costs	April 2003	1,003	50	1,053	23	763
Semi-automated ECG processing software						
Initial costs	February 2004	449	361	810	17	186
Enhancements	October 2004	380	□	380	8	24
Additional Enhancements	May 2005	124	□	124	□	
Upgrade to EXPeRT®	January 2006 (estimated)	2,171	1,139	3,310	□	□
Total		\$ 6,745	\$ 2,963	\$ 9,708	\$ 124	\$ 3,889

For the year ended December 31, 2004, our financing activities used cash of \$25.6 million compared to \$3.1 million provided by financing activities during the year ended December 31, 2003. The change was primarily the result of the purchase of approximately 2 million shares of our stock for \$28.2 million under a stock buyback program during the year ended December 31, 2004.

We have a line of credit arrangement with Wachovia Bank, National Association totaling \$3.0 million. At December 31, 2004, we had no outstanding borrowings under the line.

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 such financings will be available or available on terms acceptable to us.

The following table presents contractual obligations information as of December 31, 2004 (in thousands):

<u>Contractual Obligations</u>	<u>Payments due by period</u>				
	<u>Total</u>	<u>Less than 1 year</u>	<u>1-3 years</u>	<u>3-5 years</u>	<u>More than 5 years</u>
Capital lease obligations	\$ 426	\$ 233	\$ 193	\$ □	\$ □
Operating leases	19,386	4,948	8,451	3,508	2,479
Total	\$ 19,812	\$ 5,181	\$ 8,644	\$ 3,508	\$ 2,479

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. We currently use the intrinsic value method to measure compensation expense for stock-based awards to our employees. Accordingly, we do not

[Back to Contents](#)

recognize any compensation expense related to stock option grants that we issue under our stock option plans. Under the new rules, we will be required to adopt a fair-value-based method for measuring the expense and this may materially impact our future reported results of operations. SFAS No. 123R is effective for most public companies' interim or annual periods beginning after June 15, 2005. We are evaluating the impact on our results from adopting SFAS No. 123R, but we expect it to be comparable to the pro forma effects of applying the original SFAS No. 123 (see Note 1 for further details).

In January 2003, the FASB issued FASB Interpretation No. 46 (FIN 46), 'Consolidation of Variable Interest Entities.' The requirements of FIN 46 for variable interest entities after January 31, 2003 were adopted on February 1, 2003. The adoption of FIN 46 did not have any impact on our consolidated financial statements. In December 2003, a modification of FIN 46 was issued (FIN 46R) which delayed the effective date until no later than fiscal periods ending after March 31, 2004 and provided additional technical clarifications to implementation issues. We currently do not have any variable interest entities as defined in FIN 46R.

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 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 will be effective for us for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. We are evaluating the impact from adopting SFAS No. 153, which is not expected to have an impact on our consolidated financial position, results of operations or cash flows.

Critical Accounting Policies

In December 2001 and December 2003, the Securities and Exchange Commission (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.

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. 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 revenues that we provide on a fee for services basis and are recognized as services are performed. The rental of cardiac safety equipment is recognized over the rental period. Sales of equipment and supplies are recognized at the time of sale. 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.

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

[Back to Contents](#)

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 value 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, 2004, we had a valuation allowance of \$2.6 million primarily related to the realization of certain deferred tax assets. See Note 6 in the Notes to Consolidated Financial Statements for more information.

Depreciation and Amortization of Long-lived Assets

We compute depreciation on our property, plant and equipment on a straight-line basis over estimated useful lives generally ranging 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 an estimated useful life of four years or less 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, and contain accounting policies and other disclosures required by generally accepted accounting principles.

Risks Related to our Business

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

[Back to Contents](#)

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

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 less cost. For example, in the September 2004 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. If drug sponsors shift towards semi-automated processing, more competitors are likely to compete

[Back to Contents](#)

with us in offering this service and more competitors may join our market, thus potentially reducing pricing and our market share. The effect of such actions may reduce our revenue and gross profit per transaction. Our results of operations in the quarter ended September 30, 2004 and for fiscal 2004 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 we anticipate that our results of operations for the quarter ending March 31, 2005 will also be adversely affected by this continued uncertainty. 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 2004. 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. In addition, our profitability will suffer if we reduce our prices in response to competitive pressures without achieving corresponding reductions in our expenses. 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, 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.

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 maintain 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, 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 one-time license offering. Despite our efforts to market an annual or

[Back to Contents](#)

otherwise recurring term license, our failure to continue selling one-time 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 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 reduce our cash reserves, cause the market price of our common stock to decline 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. In October 2004, we announced that we would not meet previously stated guidance for the third quarter of 2004 and in March 2005, we announced that we anticipated we would be significantly below our previously stated guidance for the quarter ending March 31, 2005. If we fail to generate the contract signings that we expect, we may fail again to meet financial guidance that we have provided, or may provide in the future, to the public.

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. In the third quarter of 2004, three studies 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

[Back to Contents](#)

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 three franchise agreements that expire in May 2006, August 2006 and December 2006, respectively. There is no assurance that we will extend these agreements beyond their existing terms.

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 trials 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 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. In April 2003, an action was initiated, naming both our Company and one of our physicians who was contracted by us to interpret ECGs during the relevant period, alleging we were negligent in the treatment of one of the plaintiffs, who was a participant in a clinical trial for which we provided services. See Item 3, Legal Proceedings. If we are found liable in this action or any other action that may be initiated in the future, 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.

[Back to Contents](#)

System failures or capacity constraints could result in the loss of or liability to clients, which could reduce our revenues and increase our expenses.

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.

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.

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. The demands of operating in such an environment may delay or prevent our development and introduction of new or enhanced products and services that

[Back to Contents](#)

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, the loss of whom could disrupt our operations, cause us to incur additional expenses and/or impede our ability to expand our operations.

The loss of the services of one or more of our key executives could negatively affect our ability to achieve our business goals. Our future performance will depend significantly on the continued service and performance of all of our executives, particularly Dr. Joel Morganroth, our Chairman of the Board of Directors and Chief Scientist, and Mr. Joseph A. Esposito, our President and Chief Executive Officer. 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 these employees.

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 and revenues. 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 EXPeR[®] 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 certain actions for damages. Although we believe the claims against us are meritless 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,

[Back to Contents](#)

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
- 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 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 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 investments.

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 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 and short-term investments, but in order to ensure liquidity, 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, 2004 would have decreased by approximately \$0.6 million. This estimate assumes that the decrease occurred on the first day of 2004 and

reduced the yield of each investment by 100 basis points. The impact on our future interest income of future

[Back to Contents](#)

changes in investment yields will depend largely on the gross amount of our cash, cash equivalents and short-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 are billed and expenses 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, 2004 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-23.

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

No disclosure required.

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 Rules 13a-15(e) or 15d-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 Rules 13a-15 or 15d-15, our disclosure controls and procedures were effective.

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 Rules 13a-15 or 15d-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

Not applicable.

[Back to Contents](#)**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 26, 2005, under the headings "Nominees for Election as Directors," "Compliance with Section 16(a) of the Exchange Act" 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

"Security Ownership of Certain Beneficial Owners and Management" in the Proxy Statement is incorporated by reference.

Existing Equity Compensation Plans

The following table presents certain information as of December 31, 2004 regarding our equity compensation plans:

Plan category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance
Equity compensation plans approved by security holders	5,381,961	\$ 5.51	1,707,860
Equity compensation plans not approved by security holders	□	□	□
Total	5,381,961	\$ 5.51	1,707,860

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.

[Back to Contents](#)

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

1. The 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 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*
 - 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.(12)
 - 10.31 Loan Agreement with Wachovia Bank, National Association.(12)
 - 10.38 Management Employment Agreement effective January 1, 2004 between Joseph Esposito and the Company.(10)*
 - 10.39 Amendment to Management Employment Agreement effective August 16, 2004 between Joseph Esposito and the Company.(12)*
 - 10.40 Amendment to Management Consulting Agreement effective January 1, 2004 between Dr. Joel Morganroth and the Company.(10)*

[Back to Contents](#)

- 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.*
- 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 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)*
- 10.52 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.
- 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.

* 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.

[Back to Contents](#)

- (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.

[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 11th day of March, 2005.

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.

Signature	Title	Date
<u>Joseph A. Esposito</u> Joseph A. Esposito	President and Chief Executive Officer, Director (Principal executive officer)	March 11, 2005
<u>Joel Morganroth</u> Joel Morganroth, M.D.	Chairman of the Board of Directors and Chief Scientist	March 11, 2005
<u>Bruce Johnson</u> Bruce Johnson	Senior Vice President and Chief Financial Officer (Principal financial and accounting officer)	March 11, 2005
<u>Sheldon M. Bonovitz</u> Sheldon M. Bonovitz	Director	March 11, 2005
<u>Gerald A. Faich</u> Gerald A. Faich	Director	March 11, 2005
<u>David D. Gathman</u> David D. Gathman	Director	March 11, 2005
<u>Elam M. Hitchner</u> Elam M. Hitchner	Director	March 11, 2005
<u>Stephen S. Phillips</u> Stephen S. Phillips	Director	March 11, 2005
<u>John M. Ryan</u>	Director	

John M. Ryan

March 11,
2005

40

[Back to Contents](#)

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS AND SCHEDULE

Report of Management		F-2
Reports of Independent Registered Public Accounting Firm		F-3
Consolidated Balance Sheets		F-5
Consolidated Statements of Operations		F-6
Consolidated Statements of Stockholders' Equity		F-7
Consolidated Statements of Cash Flows		F-8
Notes to Consolidated Financial Statements		F-9
Financial Statement Schedule:		
II. Valuation and Qualifying Accounts		F-23

F-1

[Back to Index](#)

Report of Management

Management's Report on Financial Statements

Our management is responsible for the preparation, integrity and fair presentation of information in our consolidated financial statements, including estimates and judgments. The consolidated financial statements presented in this report have been prepared in accordance with accounting principles generally accepted in the United States of America. Our management believes the consolidated financial statements and other financial information included in this report fairly present, in all material respects, our financial condition, results of operations and cash flows as of and for the periods presented in this report. The consolidated financial statements have been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report, which is included herein.

Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining an adequate system of internal control over financial reporting. Our system of internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with accounting principles generally accepted in the United States of America.

Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect our transactions and dispositions of our assets;
- provide reasonable assurance that our transactions are recorded as necessary to permit preparation of our financial statements in accordance with accounting principles generally accepted in the United States of America, and that our receipts and expenditures are being made only in accordance with authorizations of our management and our directors; and
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance and may not prevent or detect misstatements. Further, because of changes in conditions, effectiveness of internal controls over financial reporting may vary over time. Our system contains self monitoring mechanisms, and actions are taken to correct deficiencies as they are identified.

Our management conducted an evaluation of the effectiveness of the system of internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this evaluation, our management concluded that our system of internal control over financial reporting was effective as of December 31, 2004. Our management's assessment of the effectiveness of our internal control over financial reporting has been audited by KPMG LLP, an independent registered public accounting firm, as stated in their report which is included herein.

Audit Committee Oversight

The Audit Committee of the Board of Directors, which is comprised solely of independent directors, has oversight responsibility for our financial reporting process and the audits of our consolidated financial statements and internal control over financial reporting. The Audit Committee meets regularly with management and with our independent registered public accounting firm (the auditors) to review matters related to the quality and integrity of our financial reporting, internal control over financial reporting (including compliance matters related to our Code of Ethics and Business Conduct), and the nature, extent, and results of the auditors' audit of our financial statements. Our auditors have full and free access and report directly to the Audit Committee. The Audit Committee recommended, and the Board of Directors approved, that the audited consolidated financial statements be included in this Form 10-K.

[Back to Index](#)

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
eResearchTechnology, Inc.:

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that eResearchTechnology, Inc. maintained effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). eResearchTechnology, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, management's assessment that eResearchTechnology, Inc. maintained effective internal control over financial reporting as of December 31, 2004, is fairly stated, in all material respects, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Also, in our opinion, eResearchTechnology, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of eResearchTechnology, Inc. and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2004, and our report dated March 11, 2005 expressed an unqualified opinion on those consolidated financial statements.

KPMG LLP

Philadelphia, Pennsylvania
March 11, 2005

[Back to Index](#)

Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders
eResearchTechnology, Inc.:

We have audited the accompanying consolidated balance sheets of eResearchTechnology, Inc. and subsidiaries as of December 31, 2004 and 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2004. In connection with our audits of the consolidated financial statements, we also have audited the consolidated financial statement schedule, "Valuation and Qualifying Accounts." These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of eResearchTechnology, Inc. and subsidiaries as of December 31, 2004 and 2003, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2004, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the effectiveness of eResearchTechnology, Inc.'s internal control over financial reporting as of December 31, 2004, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 11, 2005 expressed an unqualified opinion on management's assessment of, and the effective operation of, internal control over financial reporting.

As discussed in Note 1 to the consolidated financial statements, the Company adopted Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets, effective January 1, 2002.

KPMG LLP

Philadelphia, Pennsylvania
March 11, 2005

[Back to Index](#)

eResearchTechnology, Inc. and Subsidiaries
Consolidated Balance Sheets
(In thousands of dollars, except per share amounts)

	December 31,	
	2003	2004
Assets		
Current Assets:		
Cash and cash equivalents	\$ 38,364	\$ 45,806
Short-term investments	13,558	22,942
Accounts receivable, net	13,947	14,798
Prepaid expenses and other	2,219	3,522
Deferred income taxes	277	323
	68,365	87,391
Total current assets		
Property and equipment, net	16,416	25,204
Goodwill	1,212	1,212
Other assets	677	782
Deferred income taxes	5,308	1,936
	\$ 91,978	\$ 116,525
	\$ 91,978	\$ 116,525
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	\$ 3,513	\$ 2,455
Accrued expenses	4,446	4,318
Income taxes payable	1,584	2,147
Current portion of capital lease obligations	644	233
Deferred revenues	12,401	20,325
	22,588	29,478
Total current liabilities		
Capital lease obligations, excluding current portion	131	193
	131	193
	131	193
Commitments and contingencies (Note 10)		
Stockholders' Equity:		
Preferred stock \$10.00 par value, 500,000 shares authorized, none issued and outstanding	-	-
Common stock \$.01 par value, 175,000,000 shares authorized, 54,735,914 and 56,396,696 shares issued, respectively	547	564
Additional paid-in capital	54,238	69,694
Accumulated other comprehensive income	1,038	1,601
Retained earnings	16,826	46,550
Treasury stock, 4,062,519 and 6,067,519 shares at cost	(3,390)	(31,555)
	69,259	86,854
Total stockholders' equity		
	\$ 91,978	\$ 116,525
	\$ 91,978	\$ 116,525

The accompanying notes are an integral part of these statements.

[Back to Index](#)

eResearchTechnology, Inc. and Subsidiaries
Consolidated Statements of Operations
(In thousands, except per share amounts)

	Year Ended December 31,		
	2002	2003	2004
Net revenues:			
Licenses	\$ 2,119	\$ 5,738	\$ 9,803
Services	31,344	46,791	76,340
Site support	8,063	14,313	23,250
Total net revenues	41,526	66,842	109,393
Costs of revenues:			
Cost of licenses	896	658	664
Cost of services	12,816	17,473	24,124
Cost of site support	4,301	6,610	11,486
Total costs of revenues	18,013	24,741	36,274
Gross margin	23,513	42,101	73,119
Operating expenses:			
Selling and marketing	6,719	7,763	9,391
General and administrative	5,695	6,804	10,103
Research and development	4,256	4,564	4,090
Total operating expenses	16,670	19,131	23,584
Operating income	6,843	22,970	49,535
Other income, net	903	310	690
Income before income taxes	7,746	23,280	50,225
Income tax provision	1,596	8,817	20,501
Net income	\$ 6,150	\$ 14,463	\$ 29,724
Basic net income per share	\$ 0.13	\$ 0.29	\$ 0.58
Diluted net income per share	\$ 0.12	\$ 0.27	\$ 0.54
Shares used to calculate basic net income per share	47,164	49,461	51,375
Shares used to calculate diluted net income per share	50,809	54,033	55,133

The accompanying notes are an integral part of these statements.

[Back to Index](#)

eResearchTechnology, Inc. and Subsidiaries
Consolidated Statements of Stockholders' Equity
(In thousands of dollars)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Retained Earnings (Accumulated Deficit)	Treasury Stock	Total
	Shares	Amount					
Balance, December 31, 2001	50,562,140	\$ 506	\$ 38,637	\$ 665	\$ (3,787)	\$ (3,229)	\$ 32,792
Comprehensive income (loss)							
Net income	□	□	□	□	6,150	□	6,150
Currency translation adjustment	□	□	□	410	□	□	410
Reclassification adjustment for unrealized gain on marketable securities	□	□	□	(665)	□	□	(665)
Total comprehensive income (loss)	□	□	□	(255)	6,150	□	5,895
Tax benefit from exercise of non-qualified stock options	□	□	686	□	□	□	686
Issuance of common stock options to non-employee	□	□	42	□	□	□	42
Cancellation of fractional shares related to stock splits	(143)	□	□	□	□	□	□
Exercise of stock options	1,017,863	10	1,155	□	□	□	1,165
Balance, December 31, 2002	51,579,860	516	40,520	410	2,363	(3,229)	40,580
Comprehensive income							
Net income	□	□	□	□	14,463	□	14,463
Currency translation adjustment	□	□	□	628	□	□	628
Total comprehensive income	□	□	□	628	14,463	□	15,091
Tax benefit from exercise of non-qualified stock options	□	□	9,903	□	□	□	9,903
Cancellation of fractional shares related to stock splits	(3,624)	□	(46)	□	□	□	(46)
Exercise of stock options	3,159,678	31	3,861	□	□	(161)	3,731
Balance, December 31, 2003	54,735,914	547	54,238	1,038	16,826	(3,390)	69,259
Comprehensive income							
Net income	□	□	□	□	29,724	□	29,724
Currency translation adjustment	□	□	□	563	□	□	563

Edgar Filing: ERESEARCHTECHNOLOGY INC /DE/ - Form 10-K

Total comprehensive income	0	0	0	563	29,724	0	30,287
Purchase of treasury stock	0	0	0	0	0	(28,165)	(28,165)
Tax benefit from exercise of non-qualified stock options	0	0	12,170	0	0	0	12,170
Share adjustment related to stock splits	1,363	0	0	0	0	0	0
Exercise of stock options	1,659,419	17	3,286	0	0	0	3,303
Balance, December 31, 2004	56,396,696	\$ 564	\$ 69,694	\$ 1,601	\$ 46,550	\$ (31,555)	\$ 86,854

The accompanying notes are an integral part of these statements.

[Back to Index](#)

eResearchTechnology, Inc. and Subsidiaries
Consolidated Statements of Cash Flows
(In thousands of dollars)

	Year Ended December 31,		
	2002	2003	2004
Operating activities:			
Net income	\$ 6,150	\$ 14,463	\$ 29,724
Adjustments to reconcile net income to net cash provided by operating activities:			
Gain on sale of marketable securities	(419)	□	□
Depreciation and amortization	3,104	5,306	8,706
Cost of sale of equipment	□	□	1,152
Provision for uncollectible accounts	□	□	171
Issuance of stock options to non-employees	42	□	□
Stock option income tax benefits	686	9,895	12,173
Changes in operating assets and liabilities:			
Accounts receivable	(932)	(6,731)	(815)
Prepaid expenses and other	(1,325)	155	(1,541)
Accounts payable	599	1,484	(1,093)
Accrued expenses	1,289	720	(524)
Income taxes	441	(2,258)	3,856
Deferred revenues	1,263	7,533	7,812
Net cash provided by operating activities	10,898	30,567	59,621
Investing activities:			
Purchases of property and equipment	(6,191)	(8,887)	(17,355)
Purchases of short-term investments	(4,057)	(12,435)	(23,351)
Proceeds from sales of short-term investments	1,816	8,184	13,967
Proceeds from sales of marketable securities	2,449	□	□
Net cash used in investing activities	(5,983)	(13,138)	(26,739)
Financing activities:			
Repayment of capital lease obligations	(459)	(601)	(720)
Proceeds from exercise of stock options	1,285	3,685	3,303
Repurchase of common stock for treasury	□	□	(28,165)
Net cash provided by (used in) financing activities	826	3,084	(25,582)
Effect of exchange rate changes on cash	338	408	142
Net increase in cash and cash equivalents	6,079	20,921	7,442
Cash and cash equivalents, beginning of year	11,364	17,443	38,364
Cash and cash equivalents, end of year	\$ 17,443	\$ 38,364	\$ 45,806

The accompanying notes are an integral part of these statements.

[Back to Index](#)

eResearchTechnology, Inc. and Subsidiaries Notes To Consolidated Financial Statements

1. Background and Summary of Significant Accounting Policies:

Background

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

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

Principles of Consolidation

The accompanying consolidated financial statements include the accounts of eRT and its wholly-owned subsidiaries. All significant intercompany accounts and transactions have been eliminated.

Reclassifications

The consolidated financial statements for prior periods have been reclassified to conform to the current period's presentation.

Use of Estimates

The preparation of financial statements in accordance with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported revenues and expenses during the reporting period. Actual results could differ from those estimates.

Revenues

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 recognize software revenues in accordance with Statement of Position 97-2, "Software Revenue Recognition," as amended by Statement of Position 98-9. 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

[Back to Index](#)

evenly over the term of service. Cardiac Safety services revenues consist of revenues that we provide on a fee for services basis as well as revenues from the rental of cardiac safety equipment. Such revenues are recognized as the services are performed or over the rental period. 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.

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 value 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.

We have recorded reimbursements received for out-of-pocket expenses incurred as revenue in the accompanying consolidated financial statements in accordance with Emerging Issues Task Force (EITF) Issue No. 01-14, "Income Statement Characterization of Reimbursements Received for Out-of-Pocket Expenses".

Cash and Cash Equivalents

We consider cash on deposit with financial institutions and all highly liquid investments with a purchased maturity of three months or less to be cash equivalents. At the balance sheet dates, cash equivalents consisted primarily of investments in money market funds.

Short-Term Investments

At December 31, 2004, short-term investments consisted of municipal securities and bonds of government sponsored agencies with maturities of less than one year. Pursuant to Statement of Financial Accounting Standards (SFAS) No. 115, "Accounting for Certain Investments in Debt and Equity Securities," available-for-sale securities are carried at fair value, based on quoted market prices, with unrealized gains and losses reported as a separate component of stockholders' equity. We classified all of our short-term investments at December 31, 2004 as available-for-sale. At December 31, 2003 and 2004, unrealized gains and losses were immaterial. Realized gains and losses during 2002, 2003 and 2004 were immaterial. For the purpose of determining realized gains and losses, the costs of the securities sold are based upon specific identification.

Marketable Securities

During the year ended December 31, 2002, we sold all of our investment in Digital Angel Corporation (DAC), a publicly traded company, at prices per share of between \$2.30 and \$6.88 and recorded a realized gain of \$0.4 million.

Property and Equipment

Property and equipment are stated at cost. Depreciation is provided using the straight-line method over the estimated useful lives of the assets ranging 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. Repair and maintenance costs are expensed as incurred. Improvements and betterments are capitalized. Pursuant to Statement of Position 98-1, "Accounting for the Costs of Computer Software Developed or Obtained for Internal Use," we capitalize costs associated with internally developed and/or purchased software systems for new products and enhancements to existing products that have reached application development stage and meet recoverability tests. These costs are included in property and equipment. Capitalized costs include external direct costs of materials and services utilized in developing or obtaining internal-use software, and payroll and payroll-related expenses for employees who are directly associated with and devote time to the internal-use software project. During the years ended December 31, 2002, 2003 and 2004, \$2.4 million, \$1.6 million and \$3.4 million, respectively, of these costs have been capitalized. As of December 31, 2004, \$3.4 million of capitalized costs have not yet been placed in service and are therefore not being amortized. We accelerated the amortization of certain internal use software costs due to an upgrade replacement that is scheduled to take place at the end of 2005 or beginning of 2006. Amortization of capitalized software development costs was \$0.4 million, \$1.4

[Back to Index](#)

million and \$2.0 million for the years ended December 31, 2002, 2003 and 2004, respectively, and is charged to cost of Cardiac Safety services. Gains or losses on the disposition of property and equipment are included in operations. Depreciation expense was \$2.7 million, \$3.9 million and \$6.7 million for the years ended December 31, 2002, 2003 and 2004, respectively.

We have conducted a review of our accounting for the leases of our office locations which were entered into at various times between 1998 and 2004. We previously accounted for tenant improvement allowances provided by the landlords as a reduction of leasehold improvements on the consolidated balance sheets. Management determined that the appropriate accounting under generally accepted accounting principles requires that the allowance be recorded as a deferred rent liability on the consolidated balance sheets and as a component of operating activities on the consolidated cash flow statements. As a result, we recorded leasehold improvements of \$1.9 million and accumulated depreciation of \$1.2 million relating to tenant allowances and a corresponding deferred rent liability of \$0.7 million at December 31, 2004. The deferred rent liability will be amortized over the lease terms as a reduction of rent expense and the additions to leasehold improvements will be amortized over the useful lives of the improvements. The cash flow statement for the year ended December 31, 2004 has also been corrected to reflect the tenant allowances received in 2004 as both a cash flow from operations and an investing activity. We corrected the lease accounting as of December 31, 2004 as we determined that the amounts are immaterial to financial statements of prior periods.

Goodwill

Effective January 1, 2002, we adopted the provisions of SFAS No. 142, "Goodwill and Other Intangible Assets." SFAS No. 142 addresses the financial accounting and reporting for acquired goodwill and other intangible assets and supersedes Accounting Principles Board (APB) Opinion No. 17, "Intangible Assets." Under SFAS No. 142, goodwill and other intangible assets with indefinite lives are not amortized but are subject to tests for impairment at least annually. In accordance with the provisions of SFAS No. 142, we ceased the amortization of goodwill effective January 1, 2002. Prior to the adoption of SFAS No. 142, we amortized goodwill over eight years.

In accordance with the provisions of SFAS No. 142, we were required to perform a transitional goodwill impairment test by June 30, 2002. In addition, SFAS No. 142 requires that we perform an impairment test annually or more frequently if events or circumstances indicate that the value of goodwill might be impaired. No goodwill impairments were recorded as a result of the SFAS No. 142 transitional impairment test or the annual impairment test completed during the fourth quarter of fiscal 2002, 2003 and 2004.

When it is determined that the carrying value of goodwill may not be recoverable, measurement of any impairment will be based on a projected discounted cash flow method using a discount rate commensurate with the risk inherent in the current business model.

Long-lived Assets

In accordance with the provisions of SFAS No. 144, "Accounting for the Impairment and Disposal of Long-Lived Assets," when events or circumstances so indicate, we assess the potential impairment of our long-lived assets based on anticipated undiscounted cash flows from the assets. Such events and circumstances include a sale of all or a significant part of the operations associated with the long-lived asset, or a significant decline in the operating performance of the asset. If an impairment is indicated, the amount of the impairment charge would be calculated by comparing the anticipated discounted future cash flows to the carrying value of the long-lived asset. At December 31, 2003 and 2004, no impairment was indicated.

Accrued Expenses

Included in accrued expenses at December 31, 2003 and 2004 was accrued compensation of \$2.6 million and \$1.3 million, respectively.

Software Development Costs

Research and development expenditures are charged to operations as incurred. SFAS No. 86, "Accounting for the Costs of Computer Software to be Sold, Leased or Otherwise Marketed," requires the capitalization of certain software development costs subsequent to the establishment of technological feasibility. Since software

[Back to Index](#)

development costs have not been significant after the establishment of technological feasibility, all such costs have been charged to expense as incurred.

Advertising Costs

We expense advertising costs as incurred. Advertising expense for the years ended December 31, 2002, 2003 and 2004 was \$1.2 million, \$0.9 million and \$0.6 million, respectively.

Stock-Based Compensation

In December 2002, SFAS No. 148, "Accounting for Stock-Based Compensation" Transition and Disclosure, was issued. SFAS No. 148 amended SFAS No. 123, "Accounting for Stock-Based Compensation," to provide alternative methods of transition for a voluntary change to the fair value based method of accounting for stock-based employee compensation. In addition, SFAS No. 148 amended the disclosure requirements of SFAS No. 123 related to the disclosures about the method of accounting for stock-based employee compensation and the effect of the method used on reported results. The disclosure provisions of SFAS No. 148 are applicable to interim or annual periods that end after December 15, 2002, and as such have been incorporated below.

SFAS No. 123, as amended by SFAS No. 148, permits companies to (i) recognize as expense the fair value of stock-based awards or (ii) continue to apply the provisions of APB Opinion No. 25, "Accounting for Stock Issued to Employees" and related interpretations, and provide pro forma net income and earnings per share disclosures for employee stock option grants as if the fair value based method defined in SFAS No. 123 had been applied. We continue to apply the provisions of APB Opinion No. 25 and provide the pro forma disclosures in accordance with the provisions of SFAS Nos. 123 and 148. Under APB Opinion No. 25, we have not recorded any stock-based employee compensation cost associated with our stock option plans, as all options granted under the plans had an exercise price equal to the market value of the underlying common stock on the date of grant.

The following table illustrates the effect on net income and earnings per share if we had applied the fair value recognition provisions of SFAS No. 123 to our stock option plans (in thousands of dollars, except per share amounts):

	Year Ended December 31,		
	2002	2003	2004
Net income, as reported	\$ 6,150	\$ 14,463	\$ 29,724
Deduct: Net stock-based employee compensation expense determined under fair value based method, net of related tax effects	(1,203)	(1,985)	(3,262)
Pro forma net income	\$ 4,947	\$ 12,478	\$ 26,462
Earnings per share:			
Basic \square as reported	\$ 0.13	\$ 0.29	\$ 0.58
Basic \square pro forma	\$ 0.10	\$ 0.25	\$ 0.52
Diluted \square as reported	\$ 0.12	\$ 0.27	\$ 0.54
Diluted \square pro forma	\$ 0.10	\$ 0.23	\$ 0.48

The weighted average fair value per share of our options granted during 2002, 2003 and 2004 was estimated as \$1.49, \$3.04 and \$9.94, respectively. The fair value of each option grant is estimated on the date of grant using the Black-Scholes option-pricing model with the following weighted average assumptions:

	2002	2003	2004
Risk-free interest rate	3.19%	2.05%	2.23%
Expected dividend yield	0.00%	0.00%	0.00%
Expected life	3 years	3 years	3 years
Expected volatility	76.90%	69.21%	66.14%

[Back to Index](#)

The effects of applying SFAS No. 123 in the pro forma disclosure may not be representative of future disclosures since the estimated fair value of stock options is amortized to expense over the vesting period and additional options may be granted in future years.

Income Taxes

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to the tax effects of operating loss and credit carryforwards and differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Other Income, Net

Other income, net consists primarily of earnings on cash, cash equivalents and short-term investments, net of interest expense related to capital lease obligations. Additionally, in 2002, we realized a net gain of \$0.4 million on the sale of marketable securities and \$47,000 of interest income on the escrow account related to the sale of the domestic clinical research operation.

Supplemental Cash Flow Information

We paid \$1.1 million, \$1.1 million and \$5.0 million for income taxes in the years ended December 31, 2002, 2003 and 2004, respectively.

During the years ended December 31, 2002, 2003 and 2004, we acquired \$1.3 million, \$0 and \$0.4 million, respectively, of property and equipment through the execution of capital leases.

Concentration of Credit Risk and Significant Clients

Financial instruments that potentially subject us to concentration of credit risk consist primarily of trade accounts receivable from companies operating in the pharmaceutical, biotechnology and medical device industries. For the year ended December 31, 2002, two clients accounted for 17.3% and 11.6% of net revenues, respectively. For the year ended December 31, 2003, one client accounted for 13.1% of net revenues. For the year ended December 31, 2004, one client accounted for 17.0% of net revenues. The loss of any such client could have a material adverse effect on our operations. We maintain reserves for potential credit losses and such losses, in the aggregate, have not historically exceeded management's expectations.

Translation of Foreign Financial Statements

Assets and liabilities of our UK subsidiary are translated at the exchange rate as of the end of each reporting period. The income statement is translated at the average exchange rate for the period. For the year ended December 31, 2003, we recorded unrealized foreign currency translation gains of \$0.6 million, which increased the accumulated balance to \$1.0 million. For the year ended December 31, 2004, we recorded unrealized foreign currency translation gains of \$0.6 million, which increased the accumulated balance to \$1.6 million.

Stock Split

On July 16, 2002, we effected a 3-for-2 split of our common stock. On May 29, 2003, we effected a 2-for-1 split of our common stock. On November 26, 2003 and May 27, 2004, we effected 3-for-2 splits of our common stock. All share and per share data have been restated to reflect these splits of our common stock as if the stock splits had occurred as of December 31, 2001.

Net Income per Common Share

Basic net income per share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the year. Diluted net income per share is computed by dividing net income by the weighted average number of shares of common stock outstanding during the year, adjusted for the dilutive effect of common stock equivalents, which consist of stock options. The dilutive effect of stock options is computed using the treasury stock method.

[Back to Index](#)

The table below sets forth the reconciliation of the numerators and denominators of the basic and diluted net income per share computations (in thousands, except per share amounts):

Year Ended December 31,	Net Income	Shares	Per Share Amount
2002			
Basic net income	\$ 6,150	47,164	\$ 0.13
Effect of dilutive shares	□	3,645	(0.01)
Diluted net income	\$ 6,150	50,809	\$ 0.12
2003			
Basic net income	\$ 14,463	49,461	\$ 0.29
Effect of dilutive shares	□	4,572	(0.02)
Diluted net income	\$ 14,463	54,033	\$ 0.27
2004			
Basic net income	\$ 29,724	51,375	\$ 0.58
Effect of dilutive shares	□	3,758	(0.04)
Diluted net income	\$ 29,724	55,133	\$ 0.54

In computing diluted net income per share, 776,700, 31,500 and 714,000 options to purchase shares of common stock were excluded from the computations for the years ended December 31, 2002, 2003 and 2004, respectively. These options were excluded from the computations because the exercise prices of such options were greater than the average market price of our common stock during the respective periods.

Comprehensive Income

SFAS No. 130, "Reporting Comprehensive Income," requires companies to classify items of other comprehensive income by their nature in the financial statements and display the accumulated balance of other comprehensive income separately from retained earnings and additional paid-in-capital in the stockholders' equity section of the balance sheet. Our comprehensive income includes net income and unrealized gains and losses from foreign currency translation and available-for-sale securities. During the year ended December 31, 2002, we sold all of our investment in DAC and eliminated the unrealized gain of \$0.7 million.

Recent Pronouncements

In December 2004, the Financial Accounting Standards Board (FASB) issued SFAS No. 123R, "Share-Based Payment." SFAS No. 123R is a revision of SFAS No. 123. 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. 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. Under the new rules, we will be required to adopt a fair-value-based method for measuring the expense and this may materially impact our future reported results of operations. SFAS No. 123R is effective for most public companies' interim or annual periods beginning after June 15, 2005. We are evaluating the impact on our results from adopting SFAS No. 123R, but we expect it to be comparable to the pro forma effects of applying the original SFAS No. 123 (see "Stock-Based Compensation" elsewhere in Note 1 for further details).

In January 2003, FASB Interpretation No. 46 (FIN 46), "Consolidation of Variable Interest Entities," was issued. The requirements of FIN 46 for variable interest entities after January 31, 2003 were adopted on February 1, 2003. The adoption of FIN 46 did not have any impact on our consolidated financial statements. In December 2003, a modification of FIN 46 was issued (FIN 46R) which delayed the effective date until no later than fiscal periods ending after March 15, 2004 and provided additional technical clarifications to implementation issues.

We currently do not have any variable interest entities as defined in FIN 46R.

In December 2004, the FASB issued SFAS No. 153, "Exchanges of Nonmonetary Assets," which eliminates an exception in APB Opinion No. 29 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 will be effective for us for nonmonetary asset exchanges occurring in fiscal periods beginning after June 15, 2005. We are evaluating the impact from adopting SFAS No. 153, which is not expected to have an impact on our consolidated financial position, results of operations or cash flows.

[Back to Index](#)**2. Sale of the Domestic CRO Operation**

On December 31, 1999, we sold the business and certain of the assets of our domestic CRO operation (the [Division]), which consisted of clinical trial management and clinical data management operations. We received cash consideration of \$1.0 million on December 31, 1999 and \$8.0 million on January 31, 2000, with additional consideration, if any, payable over time, subject to adjustments and earn-outs.

3. Accounts Receivable

The components of accounts receivable are as follows (in thousands):

	December 31,	
	2003	2004
Billed	\$ 14,074	\$ 15,210
Unbilled	240	□
Allowance for doubtful accounts	(367)	(412)
	<u>\$ 13,947</u>	<u>\$ 14,798</u>

4. Property and Equipment

The components of property and equipment are as follows (in thousands):

	December 31,	
	2003	2004
Computer and other equipment	\$ 20,383	\$ 26,823
Furniture and fixtures	2,742	2,907
Leasehold improvements	1,543	3,878
System development costs	6,327	9,708
Construction in process	□	1,703
	<u>30,995</u>	<u>45,019</u>
Less-Accumulated depreciation	(14,579)	(19,815)
	<u>\$ 16,416</u>	<u>\$ 25,204</u>

5. Line of Credit

We have a line of credit with a bank, through June 30, 2005, that provides for borrowings up to \$3.0 million at an interest rate equal to the one-month LIBOR plus 1.75%. The line of credit agreement includes certain covenants, the most restrictive of which limit future indebtedness and require compliance with a liabilities-to-tangible net worth ratio. To date, we have not borrowed any amounts under our line of credit.

[Back to Index](#)**6. Income Taxes**

The income tax provision consists of the following (in thousands):

	Year Ended December 31,		
	2002	2003	2004
Current provision:			
Federal	\$ □	\$ 8,752	\$ 11,798
State and local	182	900	4,547
Foreign	995	1,933	830
	<u>1,177</u>	<u>11,585</u>	<u>17,175</u>
Deferred provision (benefit):			
Federal	1,185	(3,692)	2,744
State and local	(932)	602	444
Foreign	166	322	138
	<u>419</u>	<u>(2,768)</u>	<u>3,326</u>
	<u>\$ 1,596</u>	<u>\$ 8,817</u>	<u>\$ 20,501</u>

Foreign income before income taxes was \$3.3 million, \$6.4 million and \$2.8 million for the years ended December 31, 2002, 2003 and 2004, respectively.

The reconciliation between income taxes at the federal statutory rate and the amount recorded in the accompanying financial statements is as follows (in thousands):

	Year Ended December 31,		
	2002	2003	2004
Tax at federal statutory rate	\$ 2,634	\$ 8,148	\$ 17,579
Increase (decrease) in valuation allowance	(1,074)	133	354
State and local taxes, net of federal	182	976	3,244
Federal tax credits	(172)	(587)	(307)
Foreign pre-tax income	33	□	□
Tax-free interest income	(24)	(18)	(37)
Other	17	165	(332)
	<u>\$ 1,596</u>	<u>\$ 8,817</u>	<u>\$ 20,501</u>

The components of our net deferred tax asset are as follows (in thousands):

	December 31,	
	2003	2004
Goodwill amortization	\$ 1,982	\$ 1,830
Capitalized R&D expenses	3,200	2,394
Tax credit carryforwards	2,041	418
Net operating loss carryforwards	926	610
Investment impairment	1,845	2,262
Reserves and accruals	395	425

Gross deferred tax assets	<u>10,389</u>	<u>7,939</u>
Repatriation of UK earnings	(107)	(265)
Depreciation	(2,419)	(2,783)
Gross deferred tax liabilities	<u>(2,526)</u>	<u>(3,048)</u>
Deferred tax assets valuation allowance	(2,278)	(2,632)
Net deferred tax assets	<u>\$ 5,585</u>	<u>\$ 2,259</u>

[Back to Index](#)

At December 31, 2004, we had net operating loss carryforwards for state and local tax purposes of approximately \$9.4 million, which will begin to expire in 2018. A valuation allowance of \$2.6 million has been provided as of December 31, 2004 primarily for the capital loss on the investment impairment. The \$0.4 million increase in the valuation allowance in 2004 was primarily related to an increase in the deferred tax asset related to the capital loss on the investment impairment. We began recognizing a deferred tax liability for undistributed earnings of our UK subsidiary beginning in 2002.

Based on our current and future estimates of pretax earnings, management believes the amount of gross deferred tax assets will more likely than not be realized through future taxable income, after consideration of the valuation allowance.

7. Employee Retirement Plan

We sponsor a 401(k) savings plan for all eligible employees of the Company. Generally, participants in this plan may contribute a portion of their compensation on either a before-tax basis, or on both a before-tax and after-tax basis. The plan also provides for mandatory and discretionary employer matching contributions at various rates. The cost of benefits under the savings plan totaled \$0.2 million in 2002, \$0.2 million in 2003 and \$0.3 million in 2004.

8. Related Party Transactions

Our Chairman, who is a stockholder, is a cardiologist who, in addition to his role as Chief Scientist of the Company, provided medical consulting services to the Company as an independent contractor through his wholly-owned professional corporation during 2002, 2003 and 2004 (see Note 10). Fees incurred under this consulting arrangement approximated \$0.4 million in each year ended December 31, 2002, 2003 and 2004. At December 31, 2003 and 2004, \$242,000 and \$208,000, respectively, was owed to the professional corporation in connection with the consulting agreement. We amended our consulting agreement with the professional corporation in January 2004 and 2005 (see Note 10).

A director of the Company is a partner of the law firm of Duane Morris LLP, which performs legal services for the Company. Fees paid by the Company for such services were \$61,000, \$75,000 and \$400,000 for the years ended December 31, 2002, 2003 and 2004, respectively.

9. Stock Option Plans

In August 1993, we established a nonqualified stock option plan (the "1993 Plan") authorizing the grant of options to acquire up to 7,428,375 shares of our common stock. The purpose of the 1993 Plan was to provide an incentive for key individuals to advance the success of the Company. The options cover the purchase of common stock of the Company at exercise prices determined by the Board of Directors, which were initially set at or above current fair value. Options granted under the 1993 Plan became fully vested 90 days after our 1997 initial public offering and expired five years from the initial public offering date. The 1993 Plan expired in 2003 and no additional options were granted thereunder during 2003, prior to its termination.

In 1996, we adopted a stock option plan (the "1996 Plan") that authorized the grant of both incentive and non-qualified options to acquire up to 3,375,000 shares of the Company's common stock. Our Board of Directors determined the exercise price of the options under the 1996 Plan. The exercise price of incentive stock options were not below fair value on the grant date. Incentive stock options under the 1996 Plan expire ten years from the grant date and are exercisable in accordance with vesting provisions set by the Board, generally over three to five years. In May 1999, the stockholders approved an amendment to the 1996 Plan that increased the number of shares which could be granted under the 1996 Plan by 4,050,000 to 7,425,000 and provided for an annual option grant of 5,000 shares to each outside director. In April 2001, the stockholders approved an amendment to the 1996 Plan that increased the number of shares which could be granted under the 1996 Plan by 2,025,000 to 9,450,000. No additional options were granted under this plan, as amended, in 2004 and none will be granted thereafter.

In May 2003, the stockholders approved a new stock option plan (the "2003 Plan") that authorized the grant of both incentive and non-qualified options to acquire up to 3,825,000 shares of our common stock and provided

[Back to Index](#)

for an annual option grant of 10,000 shares to each outside director. The Compensation Committee of our Board of Directors determines the recipients of option grants, the exercise price and other terms of the options under the 2003 Plan. The exercise price of incentive stock options will not be below fair value on the grant date. Incentive stock options under the 2003 Plan expire ten years from the grant date, or at the end of such shorter period as may be designated by the Compensation Committee, and are exercisable in accordance with vesting provisions set by the Compensation Committee, generally over four years.

Information with respect to outstanding options under our plans is as follows:

	Outstanding Shares	Option Price Per Share	Weighted Average Exercise Price
Balance, December 31, 2001	8,426,898	\$ 0.34-2.41	\$ 1.19
Granted	1,325,813	2.37-4.21	2.89
Exercised	(1,017,863)	0.34-3.01	1.15
Cancelled	(679,158)	0.34-3.01	1.81
Balance, December 31, 2002	8,055,690	0.55-4.21	1.43
Granted	1,746,000	5.86-19.31	6.51
Exercised	(3,159,678)	0.55-3.01	1.23
Cancelled	(184,218)	0.65-6.29	3.33
Balance, December 31, 2003	6,457,794	0.55-19.31	2.85
Granted	714,411	13.88-28.57	21.99
Exercised	(1,659,419)	0.55-6.29	1.99
Cancelled	(130,825)	0.65-22.09	8.69
Balance, December 31, 2004	5,381,961	0.65-28.57	5.51

As of December 31, 2004, 2,556,752 options with a weighted average exercise price of \$2.94 per share were exercisable and 1,707,860 options were available for future grants under the 2003 Plan.

The following table summarizes information about stock options outstanding at December 31, 2004:

Range of Exercise Prices	Outstanding		Exercisable		
	Number of Options	Weighted Average Remaining Years of Contractual Life	Weighted Average Exercise Price	Number of Options	Weighted Average Exercise Price
\$0.65 - \$2.86	2,754,395	5.7	\$ 1.25	1,903,675	\$ 1.34
\$2.87 - \$5.71	486,447	7.6	3.30	157,721	3.35
\$5.72 - \$8.57	1,413,358	8.3	6.23	394,107	6.25
\$8.58 - \$11.43	13,500	8.6	10.83	3,375	10.83
\$11.44 - \$14.29	2,500	9.8	13.88	-	-
\$17.14 - \$20.00	118,125	9.1	19.74	97,874	19.82
\$20.01 - \$22.86	571,136	9.1	22.09	-	-
\$22.87 - \$28.57	22,500	9.5	28.57	-	-
	5,381,961	7.0	5.51	2,556,752	2.94

10. Commitments and Contingencies

Leases

We lease office space and certain equipment. While the majority of the leases are operating leases, certain Cardiac Safety equipment is leased under capital leases. Rent expense, net of sublease rentals, for all operating leases for the years ended December 31, 2002, 2003 and 2004 was \$2.3 million, \$3.1 million and \$4.4 million, respectively.

[Back to Index](#)

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

We entered into a lease for a separate facility in Bridgewater, New Jersey, which commenced on May 1, 1999 and expires on April 30, 2006. In 2000, we entered into a sublease agreement to lease this facility to a third party, which commenced on February 1, 2001 and expires on April 30, 2006.

Future minimum lease payments as of December 31, 2004 are as follows (in thousands):

	Capital Leases	Gross Operating Leases	Sublease Income
2005	\$ 239	\$ 4,948	\$ 324
2006	153	4,842	104
2007	40	3,609	□
2008	□	2,115	□
2009	□	1,393	□
2010 and thereafter	□	2,479	□
	<u>\$ 432</u>	<u>\$ 19,386</u>	<u>\$ 428</u>
Less imputed interest	(6)		
Net present value of capital lease obligations	426		
Less current installments	(233)		
Long-term capital lease obligations, excluding current installments	<u>\$ 193</u>		

Indemnification

We license software to our customers under written agreements. Each agreement contains the relevant terms of the contractual arrangement with the customers, and generally includes provisions for indemnifying the customers against losses, expenses, and liabilities from damages that may be awarded against the customer in the event the software is found to infringe upon certain intellectual property rights of a third party. The agreement generally limits the scope of remedies for such indemnification obligations in a variety of industry-standard respects. We have not identified any losses that are probable under these provisions and, accordingly, no liability related to these indemnification provisions has been recorded.

Agreements with the Company's Management

In addition to an employment agreement with the Company's Chairman and Chief Scientist, we entered into a consulting agreement with his wholly-owned professional corporation commencing May 21, 2001. Either party may terminate the agreement at any time, with or without cause. The consulting agreement relates to the Chairman and Chief Scientist's capacity as a medical doctor and cardiologist and, among other things, requires him to advise the Company on matters related to the successful operation, marketing and business development of its Cardiac Safety services operations. From inception to December 2002, compensation under the consulting agreement was \$180,000 per year plus discretionary bonuses of \$48,000 per year and other discretionary bonuses. The consulting agreement was amended effective January 1, 2003 to provide for compensation of \$228,000 per year plus discretionary bonuses to be determined by the Compensation Committee of our Board of Directors. A discretionary bonus of \$166,000 was awarded under the consulting agreement for the year ended December 31, 2003. The consulting agreement was further amended effective January 1, 2004 to provide for compensation of \$240,000 per year plus discretionary bonuses to be determined by the Compensation Committee of our Board of Directors. A discretionary bonus of \$128,000 was awarded under the consulting agreement for

the year ended

F-19

[Back to Index](#)

December 31, 2004. The consulting agreement was further amended effective January 1, 2005 to provide for compensation of \$264,000 per year plus discretionary bonuses to be determined by the Compensation Committee of our Board of Directors.

We entered into an employment agreement with our Chief Executive Officer effective January 1, 2004 and later amended on August 20, 2004. Under this agreement, we may terminate his employment with or without cause (as defined therein) at any time. In the event (i) that we terminate his employment other than for cause; (ii) of a change of control (as defined therein) of the Company; or (iii) of his death or disability (as defined therein), we are obligated to (x) pay him, in lump sum, one year salary and bonus; (y) to continue his benefits (as defined therein) for one year, subject to benefit plan restrictions; and (z) accelerate the vesting of all of his stock options, not otherwise vested, to purchase our common stock. The agreement further provides that, upon such change of control, Mr. Esposito shall be entitled to received the benefits described in the foregoing sentence only if either (i) he accepts employment offered at the time of the change of control by either us or the other party to the change of control (the "Buyer") for a period of up to 12 months, as determined by us or the Buyer, immediately following the change of control in a position with comparable compensation and location and with responsibilities relating to the business of the Company as conducted by the Company, the Buyer or any division or subsidiary thereof after the change of control no less than his responsibilities with us immediately prior to the change of control or (ii) neither we nor the Buyer shall offer him such a position and he resigns his employment within 60 days after the change of control. The fact that he may not be offered the position of Chief Executive Officer following any change of control will not conclusively determine whether the position offered does not include comparable responsibilities. Pursuant to the agreement, Mr. Esposito has agreed, for a period of no less than one year after termination of employment, to refrain from (i) working with a company that directly competes with us; and (ii) interfering with our business by soliciting customers or employees.

We entered into employment agreements with each of the other executive officers in 2004. Under these agreements, we may terminate their employment with or without cause (as defined therein) at any time. In the event (i) that we terminate an officer's employment other than for cause, death or disability; or (ii) of a change of control (as defined therein) of the Company, we are obligated to (x) pay the officer, in lump sum, six months to one year in salary and prorated bonus; (y) to continue the officer's benefits (as defined therein) for six months to one year, subject to benefit plan restrictions; and (z) accelerate the vesting of all of the officer's stock options, not otherwise vested, to purchase our common stock. The agreement further provides that, upon such change of control, the officer shall be entitled to receive the benefits described in the foregoing sentence only if either (i) the officer resigns his/her employment within 60 days after the change of control because neither we nor the other party to the change of control (the "Buyer") offers the officer a position with comparable responsibilities, authority, location and compensation; or (ii) the officer is employed by us or the Buyer, or a division or subsidiary thereof, for one year after the date of the change in control. Pursuant to the agreement, each officer has agreed, for a period of no less than one year after termination of employment, to refrain from (i) working with a company that directly competes with us; and (ii) interfering with our business by soliciting customers or employees.

Contingencies

We are involved in legal proceedings from time to time in the ordinary course of our business. We believe that none of these legal proceedings will have a material adverse effect on our financial condition or results of our operations.

11. Fair Value of Financial Instruments

Our financial instruments, including cash and cash equivalents, short-term investments, accounts receivable, accounts payable and capital leases are carried at cost, which approximates fair value due to the relatively short maturity of those instruments.

12. Operating Segments and Geographic Information

Since 2003, we consider our operations to consist of one segment. The development of the one segment approach corresponds to the implementation of our refinement in strategic focus in late 2002, and represents management's view of our operations. Prior to 2003, our reportable segments were Cardiac Safety and Clinical

[Back to Index](#)

Research Technology and Services. All prior periods have been restated to conform to the current-year presentation.

We operate on a worldwide basis with two locations in the United States and two locations in the United Kingdom, which is categorized below as North America and Europe, respectively. Revenues are recognized where the work is performed and not based upon the location of the client or the study.

Geographic information is as follows (in thousands):

Year Ended December 31, 2002

	North America	Europe	Total
License revenues	\$ 2,022	\$ 97	\$ 2,119
Service revenues	24,160	7,184	31,344
Site support revenues	5,448	2,615	8,063
Net revenues from external customers	\$ 31,630	\$ 9,896	\$ 41,526
Operating income	\$ 3,542	\$ 3,301	\$ 6,843
Long-lived assets	\$ 11,982	\$ 605	\$ 12,587
Identifiable assets	\$ 47,368	\$ 6,024	\$ 53,392

Year Ended December 31, 2003

	North America	Europe	Total
License revenues	\$ 4,974	\$ 764	\$ 5,738
Service revenues	36,426	10,365	46,791
Site support revenues	10,596	3,717	14,313
Net revenues from external customers	\$ 51,996	\$ 14,846	\$ 66,842
Operating income	\$ 16,574	\$ 6,396	\$ 22,970
Long-lived assets	\$ 13,264	\$ 3,152	\$ 16,416
Identifiable assets	\$ 83,834	\$ 8,144	\$ 91,978

Year Ended December 31, 2004

	North America	Europe	Total
License revenues	\$ 8,491	\$ 1,312	\$ 9,803
Service revenues	66,490	9,850	76,340
Site support revenues	19,217	4,033	23,250
Net revenues from external customers	\$ 94,198	\$ 15,195	\$ 109,393
Operating income	\$ 46,733	\$ 2,802	\$ 49,535
Long-lived assets	\$ 16,510	\$ 8,694	\$ 25,204
Identifiable assets	\$ 106,142	\$ 10,383	\$ 116,525

F-21

[Back to Index](#)**13. Quarterly Financial Data (Unaudited)**

The quarterly data below includes all adjustments (consisting only of normal recurring adjustments) that we consider necessary for a fair presentation (in thousands, except per share data).

	March 31,		June 30,		September 30,		December 31,	
	2003	2004	2003	2004	2003	2004	2003	2004
Net revenues:								
Licenses	\$ 1,189	\$ 2,453	\$ 1,154	\$ 2,670	\$ 2,513	\$ 2,675	\$ 882	\$ 2,005
Services	9,651	18,010	10,669	20,308	11,279	19,845	15,192	18,177
Site support	2,743	5,629	2,953	5,186	3,672	5,484	4,945	6,951
Total net revenues	13,583	26,092	14,776	28,164	17,464	28,004	21,019	27,133
Cost of revenues:								
Cost of licenses	144	122	188	231	185	163	141	148
Cost of services	3,807	5,985	4,095	6,081	4,628	6,053	4,943	6,005
Cost of site support	1,380	2,363	1,535	2,582	1,678	3,050	2,017	3,491
Total costs of revenues	5,331	8,470	5,818	8,894	6,491	9,266	7,101	9,644
Gross margin	8,252	17,622	8,958	19,270	10,973	18,738	13,918	17,489
Operating income	3,856	12,046	4,325	13,514	6,089	12,611	8,700	11,364
Net income	2,455	7,268	2,769	8,132	3,873	7,360	5,366	6,964
Basic net income per share	\$ 0.05	\$ 0.14	\$ 0.06	\$ 0.16	\$ 0.08	\$ 0.14	\$ 0.11	\$ 0.14
Diluted net income per share	\$ 0.05	\$ 0.13	\$ 0.05	\$ 0.15	\$ 0.07	\$ 0.13	\$ 0.10	\$ 0.13

F-22

[Back to Index](#)

SCHEDULE II
eResearchTechnology, Inc. and Subsidiaries
VALUATION AND QUALIFYING ACCOUNTS
 Allowance for Doubtful Accounts (in thousands)

	Balance Beginning of Period	Charges to Expense	Deductions from Reserve	Balance End of Period
December 31, 2002	\$ 450	□	\$ 11(a)	\$ 439
December 31, 2003	\$ 439	□	\$ 72(a)	\$ 367
December 31, 2004	\$ 367	\$ 171	\$ 126(a)	\$ 412

(a) Write-off of individual accounts receivable.

F-23
